

The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Table of Contents

35		
36	I. Introduction.....	1
37	II. Background.....	2
38	III. Overview.....	3
39	IV. Scope of This Guidance.....	5
40	V. Development of the ASCA Pilot.....	6
41	A. General Purpose of the ASCA Pilot.....	6
42	B. Specific Goals of the ASCA Pilot.....	8
43	C. Stakeholder Input on the ASCA Pilot.....	9
44	D. Noted Terminology in the ASCA Pilot.....	10
45	E. Conformity Assessment Resources Leveraged in the ASCA Pilot.....	12
46	VI. Roles and Responsibilities.....	14
47	A. Accreditation Bodies.....	14
48	B. Testing laboratories.....	14
49	C. Device Manufacturers.....	15
50	D. FDA Staff.....	15
51	VII. Selected Device Standards.....	16
52	A. Biological Evaluation of Medical Devices.....	16
53	B. Basic Safety and Essential Performance of Medical Electrical Equipment, Medical	
54	Electrical Systems, and Laboratory Medical Equipment.....	17
55	VIII. Accreditation Body and Testing Laboratory Participation.....	18
56	A. Qualifications.....	18
57	B. Application Process.....	20
58	C. Changes to Scope of Recognition.....	21
59	D. Requests for Clarification.....	26
60	E. Audits.....	27
61	IX. Use of the ASCA Pilot by Device Manufacturers.....	27
62	X. FDA Staff Premarket Review Considerations for the ASCA Pilot.....	29
63	Appendix A: ASCA Program Specifications for the Biological Evaluation of Medical Devices	31
64	Appendix B: ASCA Program Specifications for Basic Safety and Essential Performance of	
65	Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment.....	42
66	Appendix C: Accreditation Body Application for ASCA Pilot Participation.....	48
67	A. Administrative Information.....	48
68	B. Scope of Recognition.....	48
69	C. Information in Support of Competence.....	48

70	D. Signed Agreement	49
71	Appendix D: Testing Laboratory Application for ASCA Pilot Participation.....	51
72	A. Administrative Information.....	51
73	B. Scope of Recognition	51
74	C. Information in Support of Competence.....	51
75	D. Signed Agreement.....	51
76	Appendix E: ASCA Summary Test Report Examples- Biological Evaluation of Medical Devices	
77	53	
78	Appendix F: ASCA Summary Test Report Examples - Basic Safety and Essential Performance	59

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot) is authorized under section 514(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).¹ In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA),² and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),³ FDA was directed to issue a draft guidance regarding the goals and implementation of the ASCA Pilot.⁴ The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (e.g., ISO/IEC

¹ 21 U.S.C. 360d(d)

² See Pub. L. 115-52

³ See also MDUFA IV Commitment Letter: <https://www.fda.gov/media/100848/download>

⁴ See section 514(d)(3)(B)

17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

This draft guidance refers to voluntary consensus standards.⁵ For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).⁶ For more information regarding use of standards in regulatory submissions, please refer to the FDA guidance titled [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)⁷ and [Standards Development and the Use of Standards in Regulatory Submission Reviewed in CBER](#).⁸

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

FDARA amended section 514 of the FD&C Act by adding a new subsection (d) titled "Pilot Accreditation Scheme for Conformity Assessment."⁹ Subsection 514(d) requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the pilot program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.¹⁰

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.¹¹ Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory or a request for additional information regarding a specific device.¹²

⁵ For the purposes of this guidance, the term 'standard' or 'standards' will be used to refer to 'consensus standard' or 'consensus standards'.

⁶ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁷ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

⁸ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation>

⁹ See Pub. L. 115-52, section 205

¹⁰ See section 514(d)(1)(B).

¹¹ See section 514(d)(2)(A).

¹² See section 514(d)(2)(A)-(B).

III. Overview

Under the ASCA Pilot’s conformity assessment scheme, recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard (*Refer to Appendices A and B*) and ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories*. ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts such testing, it may provide a complete test report to the device manufacturer containing the elements listed in Appendices A and B of this guidance. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity with supplemental documentation (including a summary test report as described in Appendices E and F) as part of a premarket submission to FDA (*Refer to Section VI. of this guidance*).

Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using a standard eligible for inclusion in the ASCA Pilot and in accordance with the ASCA program specifications for that standard.

The ASCA Pilot includes participation from accreditation bodies, testing laboratories, device manufacturers, and FDA staff as described below and shown in Figure 1. Each of these entities plays a critical role in the ASCA Pilot to ensure that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices.

To participate in the ASCA Pilot, accreditation bodies and testing laboratories apply to FDA (*Refer to Section VIII.B. of this guidance*) to demonstrate that they have the qualifications for their respective roles within the pilot (*Refer to Section VIII.A. of this guidance*). An application includes agreement to the terms of participation outlined in Section D of Appendices C and D. For example, a participating accreditation body or testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. FDA *recognizes* qualified applicants as participants.¹³ In its recognition, FDA will identify the *scope* of specific standards and test methods to which each participant may accredit or test as part of the ASCA Pilot (*Refer to Section VIII.B. of this guidance*).

After recognizing a testing laboratory as a participant in the ASCA Pilot, FDA will generally grant the testing laboratory *ASCA Accreditation* (*Refer to Section VIII.B. of this guidance*). During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories that a medical device is in conformity with the specified testing to a particular standard, and does not intend to review complete test reports from ASCA-accredited

¹³ The ASCA Pilot uses the terms “recognition:” and “accreditation” in specific ways described below and in Section V.D. of this guidance.

testing laboratories in support of a declaration of conformity submitted with a premarket submission except in the below circumstances:

- As part of a periodic audit;¹⁴ or
- If the summary test report indicates an issue with the testing or device (e.g., controls do not perform as expected, or test results indicate a potential issue with safety or performance);¹⁵ or
- If FDA becomes aware of information materially bearing on the safety or effectiveness of the device¹⁶ (e.g., if the testing laboratories under the purview of 21 CFR 58 receive from FDA Bioresearch Monitoring Program a warning letter including issues that could potentially impact the testing in their scope or if specific use issues of public health concern are identified for a device type during total product lifecycle reviews).

Note that *ASCA Accreditation* is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Pilot. FDA's decision to recognize the accreditation for purposes of the ASCA Pilot is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Pilot.

FDA may withdraw recognition from a testing laboratory or accreditation body or suspend a testing laboratory's *ASCA Accreditation* if we identify issues that require correction or become aware of information materially bearing on safety or effectiveness of a device assessed for conformity by a testing laboratory so accredited. (*Refer to Section VIII.C. of this guidance*) If FDA suspends a testing laboratory's *ASCA Accreditation* or withdraws their recognition, an accreditation body's own decision regarding that laboratory is not necessarily affected. An accreditation body may continue to accredit the testing laboratory, however, FDA would no longer recognize that accreditation for purposes of the ASCA Pilot.

As part of the enactment of MDUFA IV, FDA committed to publish a list of accreditation bodies and testing laboratories participating in the ASCA Pilot,¹⁷ including the standards within their scopes of recognition, on the FDA's ASCA website.¹⁸ Device manufacturers may choose to use a testing laboratory participating in the ASCA Pilot to conduct testing for premarket submissions to FDA. As noted above, reports in premarket submissions from ASCA-accredited testing laboratories will generally be accepted unless summary test reports indicate an issue with the testing or device. It is the manufacturer's responsibility to ensure standards are selected and used appropriately and that the declarations of conformity provided in a premarket submission is

¹⁴ See section 514(d)(2)(A).

¹⁵ See section 514 (d)(1)(B).

¹⁶ See section 514(d)(2)(B).

¹⁷ MDUFA IV Commitment Letter: <https://www.fda.gov/media/100848/download>

¹⁸ ASCA website: <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>

consistent with the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”¹⁹



Figure 1 Process flow for the ASCA Pilot. “AB” refers to “accreditation body” and “TL” refers to “testing laboratory.”

Questions about the ASCA Pilot, including the standards identified as eligible within the pilot as well as the application processes and decisions, may be directed to ASCA@fda.hhs.gov.

IV. Scope of This Guidance

This draft guidance describes the goals and implementation of the ASCA Pilot as required by section 514(d)(3)(B). Specifically:

- The “criteria specified by the Secretary”²⁰ used to determine whether and how an accreditation body or testing laboratory may participate in the ASCA Pilot. These criteria include:
 - Qualifications FDA intends to consider when reviewing applications from accreditation bodies and testing laboratories to participate in the ASCA Pilot (*Refer to Section VIII.A. of this guidance*);
 - Processes the FDA intends to follow, including recommended application contents, in recognizing accreditation bodies and testing laboratories as participating in the ASCA Pilot (*Refer to Section VIII.B. of this guidance*).
 - Terms of participation that accreditation bodies and testing laboratories agree to as participants in the ASCA Pilot (*Refer to Section D of Appendices C and D*); and
 - ASCA program specifications associated with each eligible standard developed to communicate expectations for how participating accreditation bodies accredit testing laboratories in the ASCA Pilot (*Refer to Appendices A and B*).
- The “certain standards recognized under [section 514]”²¹ eligible for inclusion in the ASCA Pilot (*Refer to Section VII. of this guidance*). Note that the MDUFA IV

¹⁹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

²⁰ See section 514(d)(1)(A).

²¹ See section 514(d)(1)(A).

Commitment Letter²² articulates considerations in selection of these standards for inclusion in the pilot.

- The process by which device manufacturers may incorporate testing from ASCA-accredited testing laboratories in a submission to FDA for the purpose of demonstrating conformance of a device with standards eligible for inclusion in the ASCA Pilot.²³ (*Refer to Section IX. and Appendices E and F of this guidance*)
- The policy regarding Agency review of determinations by ASCA-accredited testing laboratories that a device conforms with standard(s) eligible for inclusion in the ASCA Pilot. Such determinations “shall be accepted by the Secretary for purposes of demonstrating such conformity under this section unless the Secretary finds that a particular such determination shall not be so accepted.”²⁴ (*Refer to Section X. of this guidance*)
- The processes and policies FDA intends to follow when “conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories.”²⁵ (*Refer to Section VIII.E. of this guidance*)
- The processes and policies FDA intends to follow regarding “suspension or withdrawal of accreditation” or “requesting additional information”²⁶ (*Refer to Section VIII.C. of this guidance*)

This guidance does not address specific content for a particular premarket submission. For more information about the use of standards for device review, visit the [Standards and Conformity Assessment Program website](#). See also FDA’s guidance, “[CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition](#)”²⁷ FDA’s guidance, “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#),” and FDA’s guidance “[Standards Development and the Use of Standards in Regulatory Submission Reviewed in CBER](#).”

This guidance document is not intended to be a complete resource for understanding conformity assessment. Key conformity assessment resources used to develop the ASCA Pilot are described in Section V.E. of this guidance.

V. Development of the ASCA Pilot

A. General Purpose of the ASCA Pilot

Evidence of conformity to one or more FDA-recognized standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and/or effectiveness. For

²² See MDUFA IV Commitment Letter pg. 14: <https://www.fda.gov/media/100848/download>

²³ See section 514(d)(1)(B).

²⁴ See section 514(d)(1)(B).

²⁵ See section 514(d)(2)(A).

²⁶ See section 514(d)(2)(A) and 514(d)(2)(B).

²⁷ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cdrh-standard-operating-procedures-identification-and-evaluation-candidate-consensus-standards-0>

manufacturers and FDA to benefit from the efficiency, however, FDA must have confidence in the declaration of conformity.²⁸ Declarations of conformity are discussed in section 514(c)(1)(B) and the guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”²⁹ These resources indicate that a device manufacturer may provide a declaration of conformity to one or more FDA-recognized standards in a premarket submission to be reviewed by FDA.

A device manufacturer may either determine conformity itself, or it may contract with an independent testing laboratory. However, in either case, the reliability of the determination varies depending on, in particular, the specific laboratory performing the testing and the standard being used (among other factors). Given this variability, and because medical devices are increasingly complex and can involve high risks to patients, declarations of conformity are not always sufficient to fully address FDA’s questions regarding safety and effectiveness for premarket authorization, especially when deviations from the standard have been introduced. As a result, FDA reviewers may need to request additional information and review complete test reports as described in the guidance document “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices”. In some instances, testing may be repeated or revised based on FDA input. These interactions and requests for modifications in test methodology can result in delays and additional costs to provide FDA with the necessary confidence in a declaration of conformity for its intended purpose.

As required by FDARA³⁰ and as part of the enactment of MDUFA IV,³¹ FDA committed to the establishment of the ASCA Pilot with stakeholder input.³² FDA held a public workshop to obtain input and recommendations from stakeholders regarding the goals, scope, procedures, and requirements for the ASCA Pilot. The feedback sought from stakeholders (*Refer to Section V.C. of this guidance*) was directed to the ultimate purpose of improving the efficiency of the premarket review process by building confidence in declarations of conformity through the utilization of accredited testing laboratories. As required by sections 514(d)(1) and 514(d)(2), during the ASCA Pilot, FDA intends to rely on recognized accreditation bodies to accredit testing laboratories using the specific conformity assessment scheme outlined in this guidance. Manufacturers may choose to include testing to an established standard included in the ASCA Pilot that is conducted by an accredited testing laboratory participating in the ASCA Pilot in their premarket submissions. When such testing is submitted to FDA, the Agency generally will accept the testing laboratory’s determinations that a device conforms with the specified standards based on the increased confidence in the reliability of the testing laboratory’s determination provided by the ASCA Pilot, which is predicated on the processes and policies outlined in this guidance. FDA does not intend to question the validity of methods and outcomes from ASCA-

²⁸ See section 514(c)(1)(B).

²⁹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

³⁰ See sections 514(d)(1) and 514(d)(3)(A)

³¹ See also MDUFA IV Commitment Letter: <https://www.fda.gov/media/100848/download>

³² 83 FR 2165, available at <https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug>

accredited testing laboratories except as part of periodic audits, if the summary test report indicates an issue with the testing or device, or if FDA becomes aware of information materially bearing on the safety or effectiveness of a device.³³ Further, if tests have concerning findings (e.g., controls do not work as expected or test results signal a possible safety issue), additional information may be requested to determine whether the findings can be used to support a decision on a premarket submission.³⁴ We believe this general approach can help minimize unnecessary regulatory burden and help FDA efficiently use our scientific resources while ensuring there is reasonable assurance of the safety and effectiveness of medical devices intended for human use.

B. Specific Goals of the ASCA Pilot

The ASCA Pilot is intended to support FDA’s public health mission by providing increased confidence in testing results from ASCA-accredited testing laboratories, as well as potentially decreasing the burden of individual premarket submissions when manufacturers rely on testing completed by ASCA-accredited testing laboratories.

The overarching goals of the ASCA Pilot are intended to:

- Enhance confidence in medical device testing

The ASCA Pilot includes application processes for accreditation and periodic audits of accreditation bodies and testing laboratories as well as the processes that will be followed for suspension or withdrawal (*Refer to Section VIII. of this guidance*). These processes and audits are intended to increase confidence in the testing performed by ASCA-accredited testing laboratories and ensure that the accreditation bodies participating in the ASCA Pilot meet the criteria specified by FDA for participation in the ASCA Pilot and continue to satisfy those criteria throughout their participation in the program.³⁵ The increased confidence in testing may be particularly helpful for premarket submissions that rely on declarations of conformity to FDA-recognized standards using ASCA-accredited testing laboratories.

- Promote consistency and predictability in the premarket review process

The ASCA Pilot does not introduce new requirements for medical device manufacturers. Rather, by clearly communicating expectations for when results from ASCA-accredited testing laboratories are included in premarket submissions, the ASCA Pilot intends to promote consistency and predictability in all of FDA’s premarket submission programs.

- Encourage effective use of FDA resources

Under the ASCA Pilot, FDA does not intend to question the validity of test methods and outcomes from ASCA-accredited testing laboratories except as part of periodic audits, if

³³ See section 514(d)(2)(A) & (B).

³⁴ See section 514(d)(1)(B).

³⁵ See section 514(d)(1)(A).

the summary test report indicates an issue with the testing or device, or if FDA becomes aware of information materially bearing on the safety or effectiveness of the device. (Note that if tests have concerning findings or the standard is not selected or used appropriately as outlined in the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)”, additional information may be requested to determine whether the findings can be used to support a decision on a premarket submission.) Increased acceptance of determinations of conformity to standards allows FDA to direct scientific and regulatory resources to other priorities.

- Enhance regulatory efficiency

By virtue of a testing laboratory’s participation in the ASCA Pilot, device manufacturers can be more confident early in the product development lifecycle that testing to the standards for which the laboratory has *ASCA Accreditation* are likely to meet FDA’s regulatory requirements. FDA expects that the application process, periodic audits, and clear communication among participants in the ASCA Pilot will decrease the potential regulatory issues identified by FDA during premarket submission review and/or retesting to address requests for additional information related to testing using standards which are eligible for inclusion as part of the ASCA Pilot.

- Support international harmonization

FDA draws upon elements from international conformity assessment standards in the ISO/IEC 17000 series to establish the ASCA Pilot. The standards within the ISO/IEC 17000 series are utilized worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers.³⁶ In addition, most of the FDA-recognized consensus standards selected for the ASCA Pilot are international consensus standards. FDA believes the experience gained in the ASCA Pilot could broadly inform international harmonization efforts such as standards utilization across jurisdictions.

C. Stakeholder Input on the ASCA Pilot

The concept of the ASCA Pilot emerged from discussions with device manufacturers during negotiations for the Medical Device User Fee Amendments for fiscal years 2018 through 2022 (MDUFA IV). As required by FDARA,³⁷ FDA committed to the establishment of the ASCA Pilot with stakeholder input. FDA has developed the framework of the ASCA Pilot with the support and participation of stakeholders from industry, the conformity assessment community, and technical experts from the National Institute of Standards and Technology (NIST).

³⁶ See NIST SP 2000-01 ABCs of Conformity Assessment (2018) available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-01.pdf>

³⁷ See section 514(d)(1) & 514(d)(3)(A).

In addition, FDA published a *Federal Register* notice³⁸ requesting comments on a set of questions designed to gain insight regarding the development and overall design/approach of the ASCA Pilot including goals, pilot standards, design concepts, and overall program approach. Comments received in response to this notice were reviewed and considered in the development of this guidance. These comments were also informative to the public meeting required by section 514(d)(3)(A).³⁹

As required by FDARA,⁴⁰ FDA held a public workshop titled “Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards” on May 22-23, 2018,⁴¹ to discuss and obtain input and recommendations from stakeholders about the ASCA Pilot, including its goals and scope as well as a suitable framework and procedures to facilitate implementation. The workshop is discussed on FDA’s “Workshop and Conferences” website.³⁸

Input from each of these resources has been informative in the design of the conformity assessment scheme and selection of the initial standards eligible for inclusion in the ASCA Pilot as discussed in this guidance.

D. Noted Terminology in the ASCA Pilot

This guidance document is not intended to be a complete resource for understanding conformity assessment. However, this section provides a limited set of key conformity assessment terms to aid in understanding the ASCA Pilot. We draw these definitions from the international standard ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles.

Some definitions within voluntary standards refer to “requirements.” FDA’s references to them for the ASCA Pilot do not make them legal or regulatory requirements.

- Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
- Accreditation body: authoritative body that performs accreditation.
- Audit: systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.
- Conformity assessment: demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled; note that the subject field of conformity

³⁸ 82 FR 22548 (May 16, 2017).

³⁹ ASCA Public Workshop website: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-accreditation-scheme-conformity-assessment-asca-medical-devices-fda-recognized>

⁴⁰ See section 514(d)(3)(A)

⁴¹ 83 FR 2165, available at <https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug>

assessment may include testing, inspection, and certification, as well as accreditation of conformity assessment bodies.

- Conformity assessment body: body that performs conformity assessment services; note that an accreditation body is not a conformity assessment body.
- Conformity assessment scheme: conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules and procedures apply.⁴²
- Conformity assessment system: rules, procedures, and management for carrying out conformity assessment.
- Third-party attestation: issue of statement, based on a decision following review, that fulfilment of specific requirements has been demonstrated.

In addition to the above definitions from ISO/IEC 17000, FDA uses the term “recognize” differently in different contexts in the ASCA Pilot.

- Standards

The term “*recognize*” in section 514(c) of the FD&C Act refers to FDA’s identification of standards as appropriate for manufacturers of products to declare conformance to meet relevant requirements under the FD&C Act, including premarket submission requirements. For more information on the standards recognition process, please visit the [Standards and Conformity Assessment Program website](#)⁴³ and review FDA’s guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”

- Accreditation bodies and testing laboratories

In the ASCA Pilot, FDA *recognizes* accreditation bodies and testing laboratories as participating in the ASCA Pilot (*Refer to section VIII.B. of this guidance*). Recognition is provided to any qualified applicant organization that agrees to the terms of participation. ASCA Pilot participation includes training, communication with FDA, periodic audits, and the other processes and policies outlined in this guidance. Throughout this guidance, FDA uses the term “recognized accreditation body” to refer to accreditation bodies that are participating in the ASCA Pilot.

Each recognition will include a “scope of recognition” that details the standards and/or test methods for which the accreditation body or testing laboratory being recognized has demonstrated competence in accreditation or testing to FDA for the purposes of the ASCA Pilot via the application process. One or more standards and/or test methods may be withdrawn from an organization’s scope of recognition (*Refer to section VIII.C.2.*).

⁴² Per ISO/IEC 17000, conformity assessment scheme setup varies based on the object of conformity assessment (e.g., medical device), the users of the scheme (e.g., regulators, medical device manufacturers), and the nature of the specific requirements being assessed (e.g., specific medical device standards).

⁴³ Standards and Conformity Assessment Program website: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program>

Note also that FDA uses the term “accreditation” for a testing laboratory differently in two different contexts in the ASCA Pilot.

- Accreditation by an accreditation body

Accreditation bodies accredit testing laboratories, for example, to the specifications of ISO 17025 and the ASCA program specifications. An accreditation body may or may not accredit a testing laboratory independent of a laboratory’s participation (or desire to participate) in the ASCA Pilot.

- *ASCA Accreditation* granted by FDA

ASCA Accreditation is FDA’s acceptance of accreditation to ISO 17025 and the ASCA program specifications by a recognized accreditation body. *ASCA Accreditation* exists only within the ASCA Pilot, and only testing laboratories recognized by FDA as participating in the ASCA Pilot may receive *ASCA Accreditation*. FDA generally will grant *ASCA Accreditation* to testing laboratories upon recognition (*refer to section VIII.B. of this guidance*). FDA intends to generally accept testing results from an ASCA-accredited testing laboratory in premarket submissions without further interaction concerning the test methods⁴⁴ except in the below circumstances:

- As part of a periodic quality audit, whereby FDA determines additional measures under the Act are appropriate;⁴⁵
- If summary test report indicates an issue with the testing or device (e.g., controls do not perform as expected, or test results indicate a potential issue with safety or performance);⁴⁶ and/or
- If FDA becomes aware of information materially relevant to the safety or effectiveness of the device⁴⁷ (e.g., if the testing laboratories under the purview of 21 CFR 58 receive from FDA’s Bioresearch Monitoring Program a warning letter including issues that could potentially impact the testing in their scope or if specific use issues are identified for a device type during total product lifecycle reviews).

E. Conformity Assessment Resources Leveraged in the ASCA Pilot

FDA sought to maximize the use of existing frameworks and arrangements in developing the ASCA conformity assessment scheme. This way, accreditation bodies and testing laboratories can participate in the ASCA Pilot by leveraging existing processes and knowledge, increasing the net benefit of participation. We also anticipate that, by using and extending existing

⁴⁴ See section 514(d)(1)(B).

⁴⁵ See section 514(d)(2)(A).

⁴⁶ See section 514(d)(1)(B).

⁴⁷ See section 514(d)(2)(B).

paradigms, the lessons learned from the ASCA Pilot will be equally applicable, and therefore beneficial, to other stakeholders (e.g., other regulatory authorities).

The conformity assessment scheme used in the ASCA Pilot leverages the following well-established set of international conformity assessment standards and arrangements that are utilized worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers:

- International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)⁴⁸

ILAC is an international organization for accreditation bodies that accredit conformity assessment bodies including testing laboratories. The accreditation bodies that are signatories to the ILAC MRA are peer evaluated in accordance with the specifications of ISO/IEC 17011 to demonstrate their competence. The ILAC MRA provides an internationally recognized process used to accept accredited test reports. One qualification for accreditation body participation in the ASCA Pilot is whether the accreditation body is a signatory to the ILAC MRA. (*Refer to Section VIII.A. of this guidance*). FDA intends to leverage ILAC MRA policies and procedures regarding accreditation body peer evaluations and internal audits by participating as an observer during these activities (*Refer to Section VIII.E. of this guidance*).

- ISO/IEC 17011:2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies* (hereafter referred to as “ISO/IEC 17011”)

This international consensus standard describes the specifications for accreditation bodies accrediting, among others, testing laboratories. Accreditation bodies conform to ISO 17011 in order to be a signatory to the ILAC MRA, a qualification for accreditation body participation in the ASCA Pilot. (*Refer to Section VIII.A. of this guidance*). FDA intends to leverage the assessments and audits conducted by accreditation bodies per ISO 17011 by participating as an observer during these activities (*Refer to Section VIII.E. of this guidance*).

- ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* (hereafter referred to as “ISO/IEC 17025”)

This international consensus standard contains specifications for laboratories to operate competently and generate valid results. Accreditation bodies use ISO 17025 along with the ASCA program specifications associated with each eligible standard to accredit testing laboratories for the ASCA Pilot. (*Refer to Section VI.A. of this guidance*). FDA intends to leverage the audits conducted by testing laboratories per ISO 17025 by participating as an observer during these activities (*Refer to Section VIII.E. of this guidance*).

⁴⁸ For more information about ILAC, visit <https://ilac.org/about-ilac/>

In addition to the above resources, FDA also leveraged the following NIST documents, which provide an overview of conformity assessment, in the design, development, and implementation scheme of the ASCA Pilot as outlined in this guidance document: [NIST SP 2000-01 ABCs of Conformity Assessment \(2018\)](#)⁴⁹ and [NIST SP 2000-02 Conformity Assessment Considerations for Federal Agencies \(2018\)](#).⁵⁰

VI. Roles and Responsibilities

A. Accreditation Bodies

Accreditation bodies participating in the ASCA Pilot accredit testing laboratories using the specifications of ISO 17025 and the ASCA program specifications associated with each eligible standard (*Refer to Appendices A and B*), thereby increasing the confidence in a testing laboratory's competence to test according to a specific medical device standard. Upon recognizing an accreditation body as a participant in the ASCA Pilot, FDA intends to provide to the accreditation body a scope of recognition describing the extent to which the accreditation body has demonstrated competence in accreditation for purposes of the ASCA Pilot. The multiple ways in which the term "recognize" is used in the ASCA Pilot is described in Section V.D. of this guidance. The qualifications and application process for accreditation bodies are described in Sections VIII.A. and B of this guidance. An accreditation body may have its recognition withdrawn before the completion of the ASCA Pilot. (*Refer to Section VIII.C for more information on withdrawals*).

The responsibilities of an accreditation body (also referred to as "terms of participation") are identified in the signed agreement section of the accreditation body application (*Refer to Section D of Appendix C*).

B. Testing laboratories

Testing laboratories participating in the ASCA Pilot perform testing in accordance with the specifications of ISO 17025 and ASCA program specifications associated with each eligible standard (*Refer to Appendices A and B*). Upon recognizing a testing laboratory as a participant in the ASCA Pilot, FDA intends to provide the testing laboratory with a scope of recognition describing the extent to which the testing laboratory has demonstrated competence in testing for purposes of the ASCA Pilot. After recognition of a testing laboratory, FDA will generally grant testing laboratories *ASCA Accreditation* (*Refer to Section VIII.B. of this guidance*). Section V.D of this guidance provides more information on the ways the terms "recognition" and "accreditation" are used in the ASCA Pilot. The qualifications and application process for testing laboratories are described in Sections VIII.A. and B of this guidance. A testing laboratory can have its recognition withdrawn or *ASCA Accreditation* suspended before the completion of the ASCA Pilot. (*Refer to Section VIII.C for more information on withdrawals and suspension*).

⁴⁹ Available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-01.pdf>

⁵⁰ Available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-02.pdf>

The responsibilities of a testing laboratory (also referred to as “terms of participation”) are identified in the signed agreement section of the testing laboratory application (*Refer to Section D of Appendix D*).

C. Device Manufacturers

Device manufacturers may voluntarily choose to use a testing laboratory participating in the ASCA Pilot to conduct testing to be included in premarket submissions to FDA. The device manufacturer is responsible for including the appropriate information regarding device testing in its premarket submission (*Refer to Section IX. of this guidance*). It is the manufacturer’s responsibility to ensure standards are selected and used appropriately and that the declaration(s) of conformity provided in a premarket submission is consistent with the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”⁵¹

As noted in the MDUFA IV Commitment Letter,⁵² a device manufacturer’s internal testing laboratory is eligible to participate in the ASCA Pilot. In determining whether to recognize a device manufacturer’s internal testing laboratory as a participant in the ASCA Pilot, FDA intends to consider the same factors used in determining whether to recognize any other testing laboratory (*Refer to Section VIII.A.2. of this guidance*). Any recognized testing laboratory (including a device manufacturer’s internal testing laboratory) is expected to follow the processes and policies of this guidance and fulfill the roles and responsibilities described in Section VI.C. of this guidance.

D. FDA Staff

FDA staff manage the ASCA Pilot, including recognition status and audits⁵³ of participating accreditation bodies and testing laboratories as well as review of information submitted by accreditation bodies and testing laboratories per their terms of participation. FDA staff are responsible for ensuring consistent implementation of the processes and policies in this guidance document and providing any training to ASCA Pilot participants necessary to (a) maintain FDA’s confidence in the testing submitted by ASCA-accredited testing laboratories and to (b) ensure that the accreditation bodies participating in the ASCA Pilot meet the criteria specified by FDA for participation in the ASCA Pilot and continue to satisfy those criteria throughout their participation in the program.⁵⁴

FDA staff conduct reviews of premarket submissions in accordance with existing statutes, regulations, and guidance. When premarket submissions include testing from an ASCA-accredited testing laboratory, FDA staff are responsible for applying the statute, section 514(d),

⁵¹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

⁵² See MDUFA IV Commitment Letter pg. 14: <https://www.fda.gov/media/100848/download>

⁵³ Per [NIST SP 2000-01 ABCs of Conformity Assessment \(2018\)](#): “Audit activities use an organized, predictable process for assessing records and other information to determine whether requirements have been fulfilled.” FDA staff’s audits will determine whether the processes and policies of this guidance document have been fulfilled.

⁵⁴ See section 514(d)(1)(A).

of the FD&C Act, and the policies described in this guidance (*Refer to Section X. of this guidance*).

The FDA staff managing the ASCA Pilot are separate and independent from the FDA staff conducting premarket reviews.

VII. Selected Device Standards

When deciding which device standards to include in the ASCA Pilot, FDA sought to maximize the benefit of the ASCA Pilot to the public health by selecting standards that manufacturers often rely upon to address significant issues of safety and/or effectiveness. FDA identified the following standards as eligible for the ASCA Pilot based on input from stakeholders at the public workshop and provided in response to the *Federal Register* notice requesting comments. In accordance with the MDUFA IV commitment letter,⁵⁵ these standards include both cross-cutting (horizontal) and device-specific (vertical) standards, are of public health significance, and have or are able to provide the means for establishing acceptance.

When manufacturers provide declarations of conformity to the below standards from ASCA-accredited testing laboratories, FDA intends generally to accept the results without requests for additional information except as part of a periodic audit or if FDA becomes aware of information materially bearing on the safety or effectiveness of the device. (If tests have concerning findings or the standard is not selected or used appropriately as outlined in the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#),” additional information may be requested to determine whether the findings can be used to support a decision on a premarket submission). As allowed under section 514(c) of the FD&C Act and further explained in FDA’s guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#),” manufacturers may continue to rely on other standards and provide declarations of conformity in premarket submissions; however, other standards will not be eligible for the benefits of the ASCA Pilot.

A. Biological Evaluation of Medical Devices

Biological evaluation assesses the biocompatibility-related risks of medical devices with direct and/or indirect contact with human tissue. When biocompatibility testing is needed as part of a premarket submission to FDA to address biocompatibility-related risks, the selected, cross-cutting biocompatibility standards listed below are relevant to many manufacturers and the device types are of significant public health importance.

- ASTM F756: *Standard Practice for Assessment of Hemolytic Properties of Materials*
- ISO 10993-4: *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
- ISO 10993-5: *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*

⁵⁵ See MDUFA IV Commitment Letter, pg. 14 at <https://www.fda.gov/media/100848/download>

- ISO 10993-10: *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11: *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- USP <151>: *Pyrogen Test*
- ISO 10993-12: *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*

The eligible test methods included in the ASCA Pilot for biological evaluation of medical devices are:

Standard	Test method(s)
ISO 10993-4*	Complement Activation
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10 ⁵⁶	Dermal Irritation, Intracutaneous Reactivity Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

* See also ISO/TS 10993-20 for information on when complement activation should be considered for anaphylaxis (Table 2, Hypersensitivity Column).

B. Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

Evaluation of safety is critical for electrically powered medical devices. The ANSI/AAMI ES60601-1 series of standards apply to devices used in patient care settings, while the IEC 61010-1 series applies to devices used in laboratory settings. These standards are used in the majority of premarket submissions for such medical devices to support device safety. These

⁵⁶ We support the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. See generally: <https://www.fda.gov/science-research/advancing-regulatory-science/vi-modernizing-safety-testing>

standards take an ‘all-hazards approach’ to device safety, encompassing electrical, mechanical, and radiation hazards, among others, in addition to hazards posed by the environment of use. Besides addressing this wide range of generic safety requirements, the IEC 60601 and 61010 series include close to 100 “particular standards” with safety requirements for specific types of devices, such as clinical thermometers, infusion pumps, infant incubators, and laboratory centrifuges.

The test methods included in the ASCA Pilot for Basic Safety and Essential Performance of medical devices and laboratory equipment are:

- ANSI/AAMI ES60601-1: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (along with the FDA-recognized collateral and particular standards in the 60601/80601 family)⁵⁷
- IEC 61010-1: *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements* (along with the FDA-recognized particular standards in the 61010 family)⁵⁷

VIII. Accreditation Body and Testing Laboratory Participation

This section describes how accreditation bodies and testing laboratories participate in the ASCA Pilot including the following:

- Qualifications FDA considers when determining whether to recognize an applicant (*Refer to Section VIII.A. of this guidance*);
- Processes for submission and review of an application to participate in the ASCA Pilot (*Refer to Section VIII.B. of this guidance*);
- Processes and policies regarding changes to scopes of recognition for participating accreditation bodies and testing laboratories (*Refer to Section VIII.C. of this guidance*);
- Mechanisms for participating accreditation bodies and testing laboratories to ask questions of FDA (*Refer to Section VIII.D. of this guidance*); and
- The processes and policies regarding FDA audits of participating accreditation bodies and testing laboratories (*Refer to Section VIII.E. of this guidance*).

A. Qualifications

FDA will consider the following factors in determining whether to recognize an accreditation body or testing laboratory as participating in the ASCA Pilot:

⁵⁷ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

1. Accreditation Body Qualifications

- a. **Does the accreditation body have a scope of ‘signatory status’ to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)?**

This factor relies on the well-established set of international standards and arrangements for conducting conformity assessment activities described in Section V.E. of this guidance. Signatories to the ILAC MRA are peer-reviewed by other ILAC signatories for competence in accrediting conformity assessment bodies, which provides confidence that testing laboratories accredited by ILAC signatories are competent in their implementation of ISO 17025 and the ASCA program specifications associated with each eligible standard.

- b. **Is the accreditation body based in the United States?**

Many accreditation bodies exist within and outside of the United States to support global conformity assessment activities. By limiting the ASCA Pilot at this stage to accreditation bodies based in the United States, FDA aims to effectively use limited resources to support successful program implementation.

- c. **Has the accreditation body agreed in writing to the terms and conditions described in Section D of Appendix C?**

The terms and conditions outlined in Section D of Appendix C are designed to ensure transparency and accountability on the part of the accreditation body in all aspects of its participation in the ASCA Pilot. An accreditation body may choose not to follow the terms of participation at any time; however, recognition as an ASCA Pilot participant is contingent upon following such terms.

2. Testing Laboratory Qualifications

- a. **Is the testing laboratory’s requested scope of recognition consistent with the scope of accreditation provided by an accreditation body recognized as participating in the ASCA Pilot?**

This factor relies on the process for recognizing accreditation bodies as participants in the ASCA Pilot and ensures that the testing laboratory is appropriately accredited. Accreditation by a recognized accreditation body to standards included in the ASCA Pilot provides confidence in the testing laboratory because FDA has determined the accreditation body is competent for the purposes of the ASCA Pilot with respect to the eligible standards. FDA’s review of the testing laboratory’s requested scope of recognition and its comparison to the scope of accreditation provided by an accreditation body (recognized as participating in the ASCA Pilot) permits FDA to ensure that a testing

laboratory participating in the ASCA Pilot has met, and continues to meet, the criteria specified by FDA for participation in the ASCA Pilot.⁵⁸

b. Has the testing laboratory agreed in writing to the terms and conditions described in Section D of Appendix D?

The terms and conditions outlined in Section D of Appendix D ensure transparency and accountability on the part of the testing laboratory in all aspects of its participation in the ASCA Pilot. A testing laboratory may choose not to follow the terms of participation at any time; however, recognition as an ASCA Pilot participant is contingent upon following such terms.

B. Application Process

An accreditation body or testing laboratory may apply to participate in the ASCA Pilot by submitting, via email to ASCA@fda.hhs.gov, documentation demonstrating how the applicant organization addresses the ASCA Pilot qualifications described in Section VIII.A. of this guidance. Appendices C and D provide more information on application contents for accreditation bodies and testing laboratories, respectively. FDA intends to acknowledge receipt of the application and provide a unique ASCA identification number used solely for tracking the application.

FDA intends to review applications from accreditation bodies and testing laboratories within 60 calendar days. After reviewing application contents, FDA intends to notify the applicant organization via email of the issues, if any, that may preclude ASCA Pilot participation so that any issues may be addressed (if possible). When review is complete, FDA intends to inform the applicant organization via email of our decision, including, for recognition, a scope and expiration date. Note that the scope will include only standards in the ASCA Pilot for which competence has been demonstrated.

After reviewing an application from a testing laboratory, FDA will document the testing laboratory's accreditation from an accreditation body recognized as participating in the ASCA Pilot, and initially may also grant *ASCA Accreditation* to the testing laboratory. Generally, FDA does not intend to question the validity of testing methods and outcomes from ASCA-accredited testing laboratories except as part of periodic audits or if FDA becomes aware of information materially relevant to safety and/or effectiveness of the device. Note that if tests have concerning findings or if a standard is not selected or used appropriately as outlined in the guidance "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)," requests for additional information may be raised to determine whether the findings can be used to support a decision on a premarket submission. Changes to scopes of recognition and *ASCA Accreditation* status are described in Section VIII.C. of this guidance.

⁵⁸ See section 514(d)(1)(A).

FDA’s decision to recognize an accreditation body or testing laboratory is discretionary. FDA may decide not to recognize an accreditation body or testing laboratory, e.g., for reasons of public health or administrative efficiency. If FDA does not recognize an accreditation body or testing laboratory as an ASCA Pilot participant, FDA intends to provide a rationale for the decision to the applicant. FDA intends to work with any interested applicant seeking recognition while maintaining quality and confidence in the ASCA Pilot.

To renew a recognition, an accreditation body or testing laboratory may apply to continue ASCA Pilot participation 6 months prior to the expiration of its recognition following the same process outlined above.

C. Changes to Scope of Recognition

The definitions, implications for ASCA Pilot activities, and procedures for three possible changes to scope of recognition are described below. (*Refer to section V.D. of this guidance for how the terms “recognition” and “ASCA Accreditation” are used in the ASCA Pilot.*)

- Expansion of an accreditation body or testing laboratory’s scope of recognition to include new standards and/or test methods.
- Withdrawal of all or part of an accreditation body or testing laboratory’s scope of recognition.⁵⁹
- Suspension of all or part of a testing laboratory’s *ASCA Accreditation*.⁶⁰

A note on the use of the terms “withdrawal” and “suspension” in this guidance: “withdrawal” connotes a permanent or broad change of status with respect to the ASCA Pilot whereas “suspension” implies a temporary or narrow change of status. Accordingly, withdrawal of recognition means that an organization is no longer a participant in the ASCA Pilot (a broad change of status). An organization whose recognition has been withdrawn would need to submit a new application to participate in the ASCA Pilot again. In contrast, suspension of *ASCA Accreditation* means that an organization continues to participate in the ASCA Pilot, but that FDA has temporarily invalidated its *ASCA Accreditation* pending the resolution of identified issues (a narrow change of status). This guidance only uses the term “suspension” in connection with a testing laboratory’s *ASCA Accreditation* (and not in connection with FDA’s recognition of a testing laboratory or an accreditation body) because, as a practical matter, suspension of an accreditation body would be equivalent to withdrawal of its recognition since interruptions to an accreditation body’s ability to accredit testing laboratories for ASCA Pilot purposes very broadly affects the ASCA Pilot. Further, although section 514(d) of the FD&C Act authorizes FDA to withdraw accreditation (in addition to suspending it), withdrawal of *ASCA Accreditation* would be, for practical purposes, a broad change of status and equivalent to withdrawal of recognition, so this guidance does not separately describe withdrawal of accreditation.

⁵⁹ See section 514(d)(2)(A)-(B).

⁶⁰ See section 514(d)(2)(A)-(B).

FDA recommends clear and transparent communication between all participants, including manufacturers, accreditation bodies, testing laboratories, and FDA regarding changes to an organization's participation in the ASCA Pilot.

FDA intends to provide an up-to-date listing of the accreditation bodies and testing laboratories participating in the ASCA Pilot, including clear identification of their scopes of recognition, on its ASCA website. *ASCA Accreditation* status will be listed for testing laboratories as applicable.

FDA may withdraw all or some of the standards or test methods included in an accreditation body or testing laboratory's scope of recognition. For example, a scope of recognition may include multiple biocompatibility tests. If an accreditation body or testing laboratory experiences issues related to only one of the specific tests within a standard series, FDA may withdraw only that specific test from the organization's scope of recognition. Once the issues resulting in the withdrawal are addressed, an accreditation body or testing laboratory may request to expand their scope of recognition to include the previously-withdrawn standard or test method (*Refer to section VIII.C.1. of this guidance*). However, if an accreditation body or testing laboratory employs policies or procedures that affect the entire organization and call into question the reliability of the organization's accreditations or test results, FDA may withdraw all of the standards included in the organization's scope of recognition.

1. Expanding the Scope of Recognition

FDA understands that accreditation bodies and testing laboratories may continually add capabilities to their programs and increase their internal expertise. FDA encourages accreditation bodies and testing laboratories to expand their scope of recognition beyond the standards and test methods included in their initial scope when additional competencies are attained. For example, a testing laboratory may initially participate in the ASCA Pilot by conducting MEM Elution Cytotoxicity testing. After some time, the testing laboratory may obtain additional equipment and resources that can also support Complement Activation testing. The testing laboratory should be encouraged to apply for an expansion to its scope of recognition to include not only MEM Elution Cytotoxicity testing, but also Complement Activation testing. In such a situation, the standards eligible for inclusion in the ASCA Pilot would not change, only the scope of an individual accreditation body or testing laboratory's recognition.

An accreditation body or testing laboratory may apply for an expansion of its scope of recognition by following the same procedures used for its initial application for recognition. That is, an accreditation body or testing laboratory may submit documentation indicating how it meets the ASCA Pilot qualifications with respect to the additional standards or test methods via email to ASCA@fda.hhs.gov. Recommended application contents are described in Appendices C and D. In addition to the contents outlined in these appendices, FDA recommends the application include the ASCA identification number for the accreditation body or testing laboratory as well as a clear statement of the current scope and the additional standards or test methods requested for inclusion as part of the expanded scope. FDA intends to use the same identification number to track all activity for a given accreditation body or testing laboratory, including changes to the scope of recognition.

An expansion of an organization's scope of recognition adds new standards or test methods to a recognized accreditation body or testing laboratory's existing scope of recognition. FDA intends to update the scope of recognition of each ASCA Pilot participant on the [ASCA website](#) as appropriate.

2. Withdrawal of Recognition

FDA may identify issues, using a variety of mechanisms, that raise concerns regarding an accreditation body's or testing laboratory's ability to adequately fulfill its role in the ASCA Pilot. As explained in Section D of Appendices C and D, the signed agreement included in an application for ASCA Pilot participation contains an agreement to permit FDA to observe and assess ASCA-related activities. A complete application also includes an agreement to provide reports and notification of any changes that may impact the organization's participation in the ASCA Pilot. FDA may also obtain information about the competence of a testing laboratory when it reviews testing results included in premarket submissions. Similarly, FDA may obtain information about the competence of an accreditation body and its adherence to the criteria specified by FDA for participation in the ASCA Pilot when it reviews and compares a testing laboratory's requested scope of recognition to the scope of accreditation provided by the accreditation body.

One purpose of the ASCA Pilot is to increase FDA's confidence in testing results and declarations of conformity provided in premarket submissions. In certain circumstances, and as authorized in section 514(d)(2), FDA may withdraw recognition of an accreditation body or testing laboratory participating in the ASCA Pilot to maintain confidence in the results submitted under the program. Withdrawal may be an appropriate measure when the findings from the periodic audits of testing laboratories or accreditation bodies suggest unreliable testing results or conformity assessments or when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which the premarket submissions included testing from an ASCA-accredited testing laboratory. The withdrawal allows FDA to maintain confidence in the ASCA Pilot while adapting to the needs and abilities of recognized accreditation bodies and testing laboratories.

The examples below describe additional issues that might decrease FDA's confidence in an accreditation body or testing laboratory. This list is not intended to be exhaustive.

- Violation of law or violation of policies outlined in this guidance

FDA's confidence in the ASCA Pilot relies on the integrity of recognized accreditation bodies and testing laboratories. FDA may consider withdrawing recognition from an accreditation body or testing laboratory if we believe, based on credible evidence, that the organization likely committed or participated in a violation of law or a violation of the policies outlined in this guidance for ASCA Pilot participants. For example, FDA may withdraw recognition of a testing laboratory as an ASCA Pilot participant if it labels testing results conducted outside of its scope of recognition as having been conducted under the ASCA Pilot.

- Failure to correct nonconformity

If an accreditation body or testing laboratory participating in the ASCA Pilot fails to satisfactorily correct a nonconformity after notification(s), recognition as an ASCA Pilot participant may be withdrawn depending on the nature of the nonconformity. For example, FDA may withdraw recognition of an accreditation body or testing laboratory if, after FDA notification, the organization continually fails to follow the terms of its signed agreement or follow ASCA Pilot processes.

- Failure to adhere to signed agreement

The qualifications and ASCA program specifications described in this guidance provide FDA the confidence in declarations of conformity submitted by manufacturers based upon the testing results from ASCA-accredited testing laboratories. The application for ASCA Pilot participation includes several items that accreditation bodies and testing laboratories agree to do as part of their participation in the ASCA Pilot (*Refer to Section D of Appendices C and D*). For example, an accreditation body agrees to notify FDA of specific changes relative to the testing laboratories it has accredited for the ASCA Pilot, or a testing laboratory agrees to provide reports to FDA containing specific information. These agreements are designed to foster continued confidence in the accreditation bodies and testing laboratories.

As with the initial decision to recognize an accreditation body or testing laboratory, the decision to withdraw recognition is discretionary. FDA may decide to withdraw recognition for other reasons not listed above.

a. Implications for ASCA activities

A withdrawal of recognition removes an accreditation body or testing laboratory from participation in the ASCA Pilot. Any activities performed after withdrawal should not be identified as being performed as part of the ASCA Pilot. Upon withdrawal of recognition, FDA will remove the testing laboratory or accreditation body from the list of recognized organizations on the [ASCA website](#). Note that the policies described in FDA's guidance "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)," regarding review of Declarations of Conformity would apply to declarations of conformity (and the need for supplemental information to support a Declaration of Conformity) prepared by testing laboratories that have been removed from the ASCA Pilot.

A withdrawal of recognition may indicate the need for FDA to take postmarket action. FDA intends to carefully consider the reason for withdrawal when determining what postmarket action, if any, is appropriate for closed premarket submissions that included testing results and/or declarations of conformity from an ASCA-accredited testing laboratory whose recognition has been withdrawn. For example, if the nature and severity of the reasons for withdrawal might have impacted the testing results and/or declarations of conformity supporting the submission decision, FDA may engage with the device manufacturer to better understand device performance and evaluation, review Medical Device Reports (MDRs) for signs of post market

performance issues, or conduct other compliance actions. In all cases, FDA intends to carefully weigh the benefits and risks to patients when considering what, if any, action should be taken.

Withdrawal of an accreditation body's recognition may affect the testing laboratories it accredited for the ASCA Pilot. Similarly, withdrawal of a testing laboratory's recognition may affect the accreditation body that accredited it, depending on the reasons for withdrawal.

b. Procedures

When recognition is withdrawn, FDA intends to send a withdrawal letter via email to the contact on record for the accreditation body or testing laboratory. The letter will include the reason for the withdrawal and, if appropriate, how the issues may be addressed in a future application for recognition.

To address a withdrawal letter, an accreditation body or testing laboratory should submit a new application for recognition following the same procedures for an initial application as outlined in this guidance. FDA recommends that the application for participation explain how all issues included in the withdrawal letter were addressed.

An accreditation body or testing laboratory may voluntarily request withdrawal of its participation in the ASCA Pilot by submitting an email to the address on the [ASCA website](#). To facilitate processing, FDA recommends that the request to withdraw from the ASCA Pilot include the ASCA identification number of the accreditation body or testing laboratory. FDA intends to confirm the withdrawal with the contact on record and update the [ASCA website](#) within 14 calendar days of receipt of a request for voluntary withdrawal.

3. Suspension of ASCA Accreditation (Testing Laboratories Only)

Section 514(d)(2) of the FD&C Act provides that FDA may suspend *ASCA Accreditation* of testing laboratories within the ASCA Pilot. Similar to withdrawal of recognition, suspension of *ASCA Accreditation* may be an appropriate measure depending on the findings from periodic audits of testing laboratories or when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which a premarket submission included testing from an ASCA-accredited testing laboratory. A suspension removes *ASCA Accreditation* from a testing laboratory while the issues resulting in the suspension are addressed. Depending on the severity of the issue identified, the same examples provided for withdrawal of recognition, may result in suspension of *ASCA Accreditation*.

a. Implications for ASCA activities

When FDA suspends *ASCA Accreditation*, a testing laboratory can continue to be recognized as an ASCA Pilot participant. However, any activities performed during a period of suspension should be identified as such when the results are submitted to FDA as part of any type of FDA submission. (*Refer to Section IX. of this guidance*) For example, a testing laboratory should indicate in its test results that the testing was conducted while its *ASCA Accreditation* was suspended.

FDA intends to carefully consider the reason for suspension when evaluating the testing results and/or declarations of conformity from a suspended testing laboratory. Note that the policies outlined in the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)” regarding review of declarations of conformity would apply to declarations of conformity from suspended testing laboratories.

b. Procedures

When FDA suspends *ASCA Accreditation*, we intend to send a letter via email to the contact on record for the testing laboratory. The letter will include the reason for the suspension and, if appropriate, how the issues may be addressed.

To address a suspension letter, a testing laboratory should send a response documenting how all issues were resolved to ASCA@fda.hhs.gov. To facilitate processing, FDA recommends the response include reference to FDA’s suspension letter and the ASCA identification number of the testing laboratory.

Once the issues that resulted in suspension have been adequately addressed to FDA’s satisfaction, the agency intends to send acknowledgement to the contact on record indicating that the *ASCA Accreditation* is no longer suspended and has been reinstated for a specified scope. FDA will update the [ASCA website](#) to ensure that it accurately reflects the scope of recognition and *ASCA Accreditation* status.

A testing laboratory may voluntarily request suspension of their *ASCA Accreditation*. Such a request should be submitted to ASCA@fda.hhs.gov. As with responses to suspension letters, FDA recommends that the request for voluntary suspension of *ASCA Accreditation* refer to the ASCA identification number of the testing laboratory. FDA intends to confirm the suspension with the contact on record and update the [ASCA website](#) within 14 calendar days of receipt of a request for voluntary suspension.

D. Requests for Clarification

A Request for Clarification is a request submitted to FDA for clarification of one or more specific ASCA program specifications from a recognized accreditation body or testing laboratory. A Request for Clarification presents a question relative to implementation of ASCA program specifications. It does not include suggestions or requests for modifications to the ASCA Pilot or hypothetical issues. The only parties that may submit a Request for Clarification are accreditation bodies and testing laboratories recognized as participating in the ASCA Pilot.

A Request for Clarification should be submitted to ASCA@fda.hhs.gov.

E. Audits

FDA intends to periodically audit accreditation bodies and testing laboratories to ensure that they are adequately fulfilling program expectations.⁶¹

As an ILAC MRA signatory, an accreditation body must agree to periodic monitoring that includes peer re-evaluations conducted every 4 years, although shorter intervals can be determined by ILAC if needed.⁶² An ILAC MRA signatory must also agree to maintain conformance to ISO/IEC 17011, which states that an accreditation body should conduct their own internal audit annually. FDA intends to leverage the existing arrangement of audits. FDA may participate as an observer during ILAC re-evaluations and request a copy of the re-evaluation report. An accreditation body should inform FDA of any pending ILAC re-evaluations in a timely manner, so that observation arrangements can be made. FDA may also request a copy of the accreditation body's annual internal audits. If FDA determines that additional audits (on-site or remote) are appropriate, FDA intends to contact the accreditation body to make such arrangements. Note that requests for additional information can be made as a result of any of the audits discussed above.

A testing laboratory must be assessed at least every 2 years by the recognized accreditation body in order to maintain conformance to ISO/IEC 17011. FDA intends to leverage the existing arrangement of audits by participating as an observer during these audits, therefore the testing laboratory should inform FDA of any pending audits (on-site or remote). A testing laboratory also conducts its own internal audit annually to maintain conformance to ISO/IEC 17025. FDA may request a copy of the audit report from the accreditation body and/or a copy of the annual internal audits from the testing laboratory. FDA intends to contact the testing laboratory to make the appropriate arrangements if we determine that additional audits (on-site or remote) are appropriate. Note that requests for additional information can be made as a result of any of the audits discussed above.

Failure to comply with the policies and processes outlined in this guidance can lead to changes in an accreditation body's or testing laboratory's scope of recognition as described in Section VIII.C of this guidance. Under section 514(d) of the FD&C Act, if FDA becomes aware of information materially bearing on the safety or effectiveness of a device assessed for conformity by an ASCA-accredited testing laboratory, we may take additional measures, such as a request for additional information, suspension of the testing laboratory's *ASCA Accreditation*, or withdrawal of the testing laboratory's recognition.

IX. Use of the ASCA Pilot by Device Manufacturers

Device manufacturers may voluntarily choose to use a testing laboratory participating in the ASCA Pilot to conduct testing included in a premarket submission. Under the ASCA Pilot, FDA does not intend to question the validity of test methods and outcomes from ASCA-accredited

⁶¹ See section 514(d)(2)(A).

⁶² See <https://ilac.org/ilac-membership/membership-criteria/> for information on membership criteria for ILAC MRA Signatories.

testing laboratories except as part of periodic audits, if the summary test report indicates an issue with the testing or device, or if FDA becomes aware of information materially bearing on the safety or effectiveness of the device. (Note that if tests have concerning findings or the standard tested to is not selected or used appropriately as outlined in the guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)”, additional information may be requested to determine whether the findings can be used to support a decision on a premarket submission.) Please see section VIII.C.2.(a) and VIII.C.3.(a) of this guidance for implications for premarket review of testing from a testing laboratory withdrawn from the ASCA Pilot (i.e. no longer participating in the pilot) or whose *ASCA Accreditation* has been suspended without withdrawal of recognition.

The ASCA Pilot does not alter the device manufacturer’s responsibility to address relevant information in the premarket submission. This includes the responsibility to document how testing supports approval or clearance, even when such testing is performed by a testing laboratory participating in the ASCA Pilot. Clear, early communication between the device manufacturer and the testing laboratory regarding the device design, its intended use, and any specific testing needs is recommended.

As mentioned in Section IV. of this guidance, this guidance document does not address specific content for a particular premarket submission. Rather this guidance document describes how a device manufacturer may incorporate testing results from a testing laboratory participating in the ASCA Pilot into its premarket submissions.

FDA recommends manufacturer’s include the following information in the cover letter for a premarket submission containing testing results from a testing laboratory participating in the ASCA Pilot.

- Clear identification of the term “ASCA”
- Name(s) of the testing laboratory(ies)
- Testing laboratory(ies)’ ASCA identifying number(s)
- Standard(s) used during testing. Note: to qualify for the benefits of the ASCA Pilot, the standards must be within the laboratory’s scope of recognition at the time of testing.

The following items in the declaration of conformity should be included in the premarket submission.

- Date(s) the testing was conducted
- Status of *ASCA Accreditation* for the testing conducted. If a recognized testing laboratory did not have *ASCA Accreditation* at the time testing was conducted, the declaration of conformity should include an explanation of how the *ASCA Accreditation* status may or may not affect the testing results.
- ASCA Summary Test Report (see Appendix E and F for examples that articulate the elements FDA recommends including for biocompatibility and basic safety and essential performance testing).

When a premarket submission includes a declaration of conformity to a recognized standard, FDA may request and review underlying data to determine safety and effectiveness.⁶³ Under the ASCA Pilot, when the submission includes the elements listed above, the validity of test methods and outcomes provided by the testing laboratory generally will be accepted to support a decision on a premarket submission without the need for additional information or interaction between FDA and the device manufacturer and/or testing laboratory concerning those methods, unless the summary test report indicates an issue with the testing or device (e.g., controls do not perform as expected, or test results indicate a potential issue with safety or performance). Premarket review considerations for the ASCA Pilot are described in more detail in Section X. of this guidance.

Device manufacturers should also review the FDA guidance document titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#),” which further describes recommended premarket submission content when an FDA-recognized standard is used.

X. FDA Staff Premarket Review Considerations for the ASCA Pilot

Use of a conformity assessment scheme to recognize, communicate with, and audit accreditation bodies and testing laboratories provides FDA increased confidence in the methods used and results reported by ASCA-accredited testing laboratories when testing is performed within their recognized scope. Within a premarket submission, FDA does not intend to review methodology(ies) for testing conducted by an ASCA-accredited testing laboratory within its recognized scope. In these circumstances, FDA intends to accept the testing results provided FDA is not aware of information that would result in suspension of *ASCA Accreditation* or withdrawal of recognition (including for the associated accreditation body), and the summary test report does not indicate an issue with the testing or device (e.g., controls perform as expected, and test results do not indicate a potential issue with safety or performance). Please see section VIII.C.2.(a) and VIII.C.3.(a) of this guidance for implications for premarket review of testing from a testing laboratory withdrawn from the ASCA Pilot (i.e., no longer participating in the pilot) or whose *ASCA Accreditation* has been suspended without withdrawal of recognition. FDA anticipates that this process may reduce FDA review time for individual submissions.

ASCA-accredited testing laboratories agree to use methodologies consistent with the standards and test methods in their recognized scope and the ASCA program specifications as part of the ASCA Pilot. For this reason, FDA generally intends to rely on the results from ASCA-accredited testing laboratories for the purpose of premarket review (i.e., generally accept a determination that a device conforms with the standard) without the need for additional information related to conformance with a standard. In addition, FDA does not intend to question the validity of test methods from ASCA-accredited testing laboratories except as part of periodic audits or if FDA becomes aware of information materially relevant to safety or effectiveness for the device. However, if tests have concerning findings (e.g., controls do not work as expected or test results

⁶³ See section 514(c)(3)(B).

1048 signal a possible safety issue), or basic administrative information is missing (e.g., product
1049 identification information or dates of testing), additional questions may be asked to determine
1050 whether the findings can be used to support a decision on a premarket submission.

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Appendix A: ASCA Program Specifications for the Biological Evaluation of Medical Devices

The following ASCA program specifications provide expectations for applicant organizations seeking to become accredited testing laboratories for the biological evaluation of medical devices under the ASCA Pilot. These specifications are specific to the ASCA Pilot and are *in addition* to those for voluntary conformity found in ISO/IEC 17025. To participate in the ASCA Pilot, a testing laboratory for biological evaluation of medical devices is expected to meet all relevant elements of ISO/IEC 17025 as well as the below ASCA program specifications identified in this Appendix to assess biocompatibility-related risks of medical devices with direct and/or indirect contact with human tissue. For readability and ease of reference, the numbering and nomenclature (including the term “requirements”) below correspond to the numbering and nomenclature of clauses/subclauses in ISO/IEC 17025. Note that the expectations below were developed with input from stakeholders at the public workshop titled “Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards.”⁶⁴ (*Refer to Section V.C. of this guidance*).

The standards included in the ASCA Pilot for Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment (*Refer to Section VII.B. of this guidance*) include more detailed information regarding test reporting (e.g., IEC test report forms (TRFs)) in comparison to the standards included in the ASCA Pilot for Biological Evaluation of Medical Devices (*Refer to Section VII.A. of this guidance*). The specificity in the existing standards is reflected in the length and detail of the corresponding ASCA program specifications.

ISO/IEC 17025 Section 4 “General requirements”

4.1 Impartiality

If any services, such as consulting, design, or research, are offered by the applicant organization, it agrees to have a policy and procedure for maintaining impartiality through separation of those services from its testing activities.

4.2 Confidentiality

There are no additional specifications above those set forth in ISO/IEC 17025.

ISO/IEC 17025 Section 5 “Structural requirements”

There are no additional specifications above those set forth in ISO/IEC 17025.

ISO/IEC 17025 Section 6 “Resource requirements”

6.1 General

There are no additional specifications above those set forth in ISO/IEC 17025.

⁶⁴ ASCA Public Workshop website: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-accreditation-scheme-conformity-assessment-asca-medical-devices-fda-recognized>

1085 6.2 Personnel

- 1086 a) The applicant organization agrees to maintain competent technical personnel that are
1087 knowledgeable in appropriate test method for the requested scope of accreditation:
- 1088 • For technicians performing in vivo tests, 1 year of relevant test experience with
1089 each standard test and:
 - 1090 - Bachelor's or associates degree in relevant science areas to the in vitro/in vivo
1091 biocompatibility testing included in the ASCA Pilot, OR
 - 1092 - a high school degree, and at least one of the following laboratory technician
1093 accreditations: Laboratory Animal Technician (LAT), Assistant Laboratory
1094 Animal Technician (ALAT), and/or Laboratory Animal Technologist
1095 (LATG).
 - 1096 • For technicians performing in vitro tests, 1 year of relevant test experience with
1097 each standard test included in the ASCA program and:
 - 1098 - Bachelor's or associates degree in relevant science areas to the in vitro/in vivo
1099 biocompatibility testing included in the ASCA Pilot.
 - 1100 • For study directors:
 - 1101 - Bachelor's or higher degree in scientific discipline; AND
 - 1102 - 2 years of relevant test experience with each standard test; AND
 - 1103 - Direction of at least 25 studies in each relevant test.
- 1104 b) The applicant organization's management agrees to be knowledgeable in applicable
1105 aspects of the FD&C Act and 21 CFR regulations pertinent to the oversight of medical
1106 devices and the criteria set out in ISO/IEC 17025:2017 and ASCA program
1107 specifications. The applicant organization further agrees to maintain a list of laboratory
1108 managers and contact information.
- 1109 c) The applicant organization agrees to:
- 1110 • Maintain a written training program for new and current technical personnel,
1111 which will include the proper procedures for applying new/updated test
1112 procedures and performing required tests.
 - 1113 • Provide current technical personnel relevant test-specific requalification training
1114 (e.g., cytotoxicity subjective scoring) every 6-12 months, or when test standards
1115 or procedures are updated or developed, as well as when responsibilities have
1116 changed.
 - 1117 • Conduct training on a periodic basis through application of training approaches,
1118 such as on-the-job training and formal classroom training, as appropriate.
 - 1119 • Maintain written records of training demonstrating that technical personnel who
1120 participate in the conduct of ASCA testing have been trained and evaluated to be
1121 competent in the performance of each ASCA test. The training includes the ability
1122 to follow test-related standard operating procedures (SOPs) and documentation,
1123 and in person hands-on training. Training may also include classroom (or online)
1124 training. Applicant organizations further agree to have predefined criteria to
1125 qualify that technical personnel (technicians and study directors) can perform
1126 assigned tasks related to the tests under the ASCA scope of recognition.

- 1127 • Establish procedures for periodic proficiency checks of technicians (e.g., blind
1128 scoring of negative and positive controls for MEM elution assays) for the tests
1129 performed under the ASCA Pilot with subjective analyses, to include when staff
1130 would require retraining (e.g., protocol non-conformance, change in assigned
1131 activities).
- 1132 • Maintain records demonstrating trainers have qualifications and at least 2 years'
1133 experience (routinely performing each relevant ASCA test) to train the technical
1134 personnel who will perform the ASCA tests.

- 1135 d) The applicant organization agrees to have procedures to establish how samples are
1136 prepared and training that includes at a minimum the following:
- 1137 • Procedures for device preparation, including:
 - 1138 - Cutting samples (if appropriate) and documentation (e.g., photographs) of any
 - 1139 particle generation prior to extraction,
 - 1140 - Determination of device surface area for extraction ratio,
 - 1141 - Use of non-surface area approaches (e.g., porous devices),
 - 1142 - Exclusion of non-contacting components from extraction,
 - 1143 - Selection of representative portions for direct contact hemocompatibility
 - 1144 studies (i.e., hemolysis, complement activation),
 - 1145 • Selection of extraction conditions (i.e., time, temperature),
 - 1146 • Assessment and documentation of changes (e.g., photographs) after extraction to
 - 1147 sample (e.g., color changes, integrity, swelling) or extract conditions (e.g., pH,
 - 1148 particles/precipitates, color changes, or turbidity),
 - 1149 • General and/or test-specific follow-up procedures when changes are noted (e.g.,
 - 1150 extract settling techniques to allow particle-free IV injections),
 - 1151 • Use of non-standard extraction approaches (e.g., fluid path approaches,
 - 1152 approaches for extremely large devices, procedures to maintain contact with
 - 1153 extraction vehicle), and
 - 1154 • Handling of extracts prior to testing (e.g., filtration, centrifugation, storage time
 - 1155 and temperature).

- 1156 e) In addition, for *in vitro* testing, the applicant organization agrees that training will include
1157 the following, at a minimum:
- 1158 • MEM elution cytotoxicity:
 - 1159 - Cell line maintenance
 - 1160 - Cell counting
 - 1161 - Cell seeding
 - 1162 - Scoring of test and control articles
 - 1163 - Mock study to assess technician competence in test performance, data
 - 1164 documentation, and result interpretation (including test-specific assessment of
 - 1165 borderline results)
 - 1166 - Minimally, biannual periodic proficiency check of negative and positive
 - 1167 control scoring, and additional technician retraining, if needed
 - 1168 • Hemolysis:
 - 1169 - Timing from blood collection to use in test
 - 1170 - Hemoglobin absorbance standard curve

- Dilution procedures and dilution factor calculations
- Sample and control preparation and documentation
- Representative sample selection (for direct contact test)
- Documentation of supernatant color and presence of dispersed pellet fragments, if any
- Documentation of pellet color
- Supernatant removal to preserve pellet
- Blank sample correction (including if an extract is colored)
- Hemolytic index calculation
- Mock study to assess technician competence in test performance, data documentation, and result interpretation
- Technician retraining, if needed
- Complement activation:
 - Serum/blood/plasma handling to minimize complement activation
 - Sample and control preparation and documentation
 - Representative sample selection
 - Small volume pipetting
 - Complement absorbance standard curve
 - Dilution procedures and dilution factor calculations
 - Exposure time
 - Complement concentration calculations
 - Test validation criteria
 - Data analysis and use of historical control data, if necessary
 - Mock study to assess technician competence in test performance, and data documentation, and result interpretation
 - Technician retraining, if needed

- f) For *in vivo* studies, as part of the general animal handling training, the applicant organization agrees that training will include the following, at a minimum:
- Test-specific animal selection criteria
 - Animal identification and traceability within and across studies (e.g., for pyrogenicity)
 - Species- and test-specific animal holding techniques
 - Test-specific acclimation techniques
 - Body weight measurement
 - Species-specific in life observations (e.g., cage accidents, decline in health, seizures, weight loss, breathing difficulties) and when veterinarian oversight should be requested
 - Test-specific data documentation, calculations, and result interpretation (including test-specific assessment of borderline results, and re-challenge or re-test criteria, when applicable)
 - Technician retraining, if needed
- g) For the following specific *in vivo* tests, the application organization agrees that training will include the following, at a minimum:
- Guinea Pig Maximization (GPMT) and Closed Patch Sensitization:

- Shaving techniques (e.g., to avoid razor burn)
- Mixing of extract and adjuvant, if applicable
- Intradermal injection (GPMT) including criteria to confirm avoidance of subcutaneous injections
- Sample application (GPMT and Closed Patch)
- Animal wrapping
- Differentiation for source of redness (e.g., true sensitization versus mechanical/adhesive irritation)
- Minimally, quarterly periodic proficiency check of positive control scoring (in live animals at least once annually)
- Technician retraining, if needed
- Intracutaneous Reactivity and Dermal Irritation:
 - Shaving techniques (e.g., to avoid razor burn)
 - Application of test samples
 - Injection technique and signs to confirm appropriate injection location
 - Differentiation for source of redness (e.g., true irritation versus possible irritation from shaving)
 - Minimally, biannual periodic proficiency check of positive response scoring (in live animals at least once annually)
 - Technician retraining, if needed
- Acute Systemic Toxicity:
 - Balance use and calibration to ensure appropriate sensitivity
 - Intraperitoneal (IP) and intravenous (IV) injection techniques and signs to confirm appropriate injection location
 - Minimally, periodic proficiency check on injection techniques if it has been more than one month between technician conduct of a study
 - Technician retraining, if needed
- Material-mediated pyrogenicity:
 - Use of pyrogen-free/depyrogenated glassware and pyrogen free saline for extraction
 - Temperature probe use and calibration to ensure appropriate sensitivity
 - Intravenous (IV) injection techniques and signs to confirm appropriate injection location
 - Technician retraining, and criteria for when retraining would be needed (e.g., adverse events, unsuccessful injections, time between successful tests)

1250 6.3 Facilities and environmental conditions

1251 Lab personnel should be aware of the FD&C Act and regulations as applicable to medical device
 1252 manufacturers. Under 21 CFR 820.50, Purchasing Controls, medical device manufacturers must
 1253 communicate as part of contracted work any environmental conditions necessary for the proper
 1254 conduct of testing done under the scope of accreditation. In addition, applicant organizations
 1255 should have policies and procedures in place to implement 21 CFR part 58, Good Laboratory
 1256 Practices, for Nonclinical Laboratory Studies.

1257 6.4 Equipment

- 1258 a) The applicant organization agrees to ensure that all equipment used for testing and
1259 evaluating devices is available and in proper working order for the requested scope of
1260 accreditation.
- 1261 b) The applicant organization agrees to ensure that its procedures address adding, deleting,
1262 modifying, or maintaining information in equipment records in an accurate and timely
1263 manner, and specify the personnel responsible for these tasks.
- 1264 c) The applicant organization agrees to ensure that its procedures specify the steps for
1265 establishing calibration intervals for each type or item of equipment, and specify criteria,
1266 steps, and approvals for extending the calibration interval of an instrument.
- 1267 d) The applicant organization agrees to have procedures to examine the effects of equipment
1268 operation outside the equipment tolerances or study specified limits (e.g., temperature
1269 excursions) on test results. The procedures identify the personnel responsible for such
1270 examination of the equipment (e.g., technicians) and determination of acceptability with
1271 respect to test validity (e.g., study directors/toxicologists), specify their responsibilities,
1272 and provide the steps for determining if the equipment variation would impact the study
1273 results, including:
- 1274 • Determining whether the effects are unacceptable (including the accept/reject
1275 criteria);
 - 1276 • Identifying the conducted tests affected;
 - 1277 • Analyzing the results impacted for these particular tests; and
 - 1278 • Determining whether retesting is required.

1279 6.5 Metrological traceability

- 1280 a) Applicant organizations agree to use specified methods and/or standards that clearly
1281 describe the following:
- 1282 • Calibration to three decimal places for spectrophotometer assessments for
1283 hemolysis and complement activation, and
 - 1284 • Particle ranges for calibration of coulter counter use for cell counting.
- 1285 b) If test-specified positive, negative, and/or reference controls are no longer able to
1286 distinguish between positive and negative responses, the applicant organization agrees to
1287 have procedures to qualify new controls.
- 1288 c) The applicant organization agrees that controls (positive/negative/reagent, if applicable)
1289 will meet assay-specific acceptance criteria.
- 1290 d) The applicant organization agrees that, when concurrent positive controls are not
1291 conducted with the test article (e.g., sensitization testing), biannual testing (i.e., within 3
1292 months of the test article) will be conducted to confirm the ability of the test system to
1293 detect a positive sensitization response. If it is determined that the periodic positive
1294 control is no longer valid, all testing conducted after the last validated positive control
1295 run cannot be submitted as part of the ASCA Pilot.

1296 6.6 Externally provided products and services

- 1297 a) The applicant organization agrees to ensure the competence of any subcontractors
1298 utilized to conduct testing under the ASCA scope of recognition. This includes ensuring
1299 the subcontractor complies with ISO/IEC 17025 and the ASCA program specifications
1300 within this Appendix.

1301 **ISO/IEC 17025 Section 7 (“Process requirements”)**

1302 7.1 Review of requests, tenders and contracts

- 1303 a) There are no additional specifications to those set forth in ISO/IEC 17025.

1304 7.2 Selection, verification and validation of methods

- 1305 a) The applicant organization agrees that its management system will include procedures
1306 governing the development, maintenance, and use of test procedures (including
1307 associated documents such as test data forms and checklists). These management system
1308 procedures include steps for:
- 1309 • Identifying the personnel responsible for developing, reviewing, and maintaining
1310 these documents
 - 1311 • Specifying the frequency of review by technical personnel and management
 - 1312 • Ensuring consistency with applicable standard(s)
 - 1313 • Ensuring test modifications are reviewed by personnel who are competent to the
1314 applicable standard(s)
 - 1315 • Identifying the types of modifications that do not need to be reviewed for
1316 confirmation prior to implementation. The applicant organization further agrees
1317 that changes to any procedures regarding the following will be confirmed with
1318 FDA and its Accreditation Body prior to implementation:
 - 1319 - Changes to sample for retesting to achieve a “passing” result
 - 1320 - pH adjustments
 - 1321 - Sample filtration or other extract manipulation
 - 1322 - Removal of documentation associated with color, turbidity or particles in the
1323 test extract, or swelling/degradation of the test article
 - 1324 - Frequency of non-concurrent control testing
 - 1325 - Changes to acceptance criteria outside the validated/qualified laboratory-
1326 specific limits (e.g., for complement activation where the standard methods do
1327 not specify acceptable limits)
 - 1328 - Changes to data calculations and presentation, if applicable (e.g., hemolytic
1329 index, irritation index, complement activation plots)
 - 1330 - Changes in the criteria for re-challenge or retesting
 - 1331 - Changes in the criteria for reportable adverse clinical observations or animal
1332 deaths
- 1333 b) The applicant organization agrees that test procedures will include or specify, as
1334 appropriate, the following:

- 1335 • Unique identification, including title, document number, revision, and effective
1336 date;
1337 • Specific test equipment to use along with their required ratings;
1338 • Warnings/caution statements to alert the operators of potential hazards;
1339 • Normal and any unusual ambient conditions (including tolerances) for tests;
1340 • Test data to be obtained and recorded;
1341 • Objective acceptance criteria for results including the essential performance
1342 required to be maintained;
1343 • Testing techniques (i.e. test methods) required to ensure consistent results;
1344 • Instructions on test conduct, including equipment operation, reagent preparation,
1345 cell line and animal handling, techniques, preparation of test samples (including
1346 instructions for sample traceability during testing, if applicable), conduct of each
1347 step of the test, data recording, and scoring assessment procedures;
1348 • Deviations from the SOP, as well as any equipment deviations and discussion of
1349 why deviations will not impact the validity of the study results.
- 1350 c) The applicant organization agrees to ensure that relevant contextual information from the
1351 intended use of the device and manufacturers essential performance specifications,
1352 including any metrological stability, are reflected in each test procedure.
- 1353 d) The applicant organization agrees to ensure that each test procedure adequately addresses
1354 all the applicable specifications of the standard for the devices being tested.
- 1355 7.3 Sampling
- 1356 a) The applicant organization agrees that the laboratory will have a sampling plan and
1357 procedures when it carries out sampling of substances, materials or products for
1358 subsequent testing or calibration. The sampling plan as well as the sampling procedure
1359 are available at the location where sampling is undertaken. Sampling plans are, whenever
1360 reasonable, based on appropriate statistical methods. The sampling process addresses the
1361 factors to be controlled to ensure the validity of the test and calibration results.
- 1362 b) The applicant organization agrees that the procedure(s) for sample preparation will meet
1363 the specifications of ISO 10993-12 and the guidance titled [Use of International Standard](#)
1364 [ISO 10993-1, "Biological evaluation of medical devices--Part 1: Evaluation and testing](#)
1365 [within a risk management process](#)"⁶⁵ and include the following:
1366 • Use of surface area/extraction volume ratio (unless mass/extract volume ratio
1367 results in equivalent or higher amount of test sample)
1368 • No dilutions of extract or test solutions, unless required for dose-dependent
1369 cytotoxicity studies
1370 • No filtration/centrifugation
1371 • No pH/osmolality adjustment
1372 • Documentation of any color changes or turbidity or particles in the extract

⁶⁵ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>

- 1373 • How representative portions are selected for hemolysis and complement
1374 activation testing, and if entire device is not used for other testing
- 1375 • How extraction vehicle volume will be determined for devices that absorb liquids
1376 (e.g., spongy devices)
- 1377 • How sample extraction ratios will be selected for devices having multiple
1378 components with different thicknesses
- 1379 • How components with different types and durations of contact will be separated
1380 for sample preparation and testing
- 1381 • Situations when pooled component samples (with same or different types or
1382 duration of tissue contact) will be allowed
- 1383 • Inclusion of only tissue contacting components (unless procedure describes how
1384 inclusion of non-tissue contacting components will be addressed in determination
1385 of extraction ratios)
- 1386 • Submersion of large devices completely in extraction vehicle
- 1387 • That the following types of devices are excluded for the ASCA Pilot: absorbable
1388 and in situ polymerizing devices, liquid devices, hydrogel devices, and devices
1389 containing nanomaterials.

1390 7.4 Handling of test or calibration items

1391 There are no additional specifications to those set forth in ISO/IEC 17025.

1392 7.5 Technical records

1393 There are no additional specifications to those set forth in ISO/IEC 17025.

1394 7.6 Evaluation of measurement uncertainty

1395 There are no additional specifications to those set forth in ISO/IEC 17025.

1396 7.7 Ensuring the validity of results

1397 To confirm the validity of the testing methods, any test-specified positive, negative, and/or
1398 reference controls allow for distinguishing between positive and negative responses. The
1399 applicant organization agrees that pre-defined criteria for positive/negative/reference control
1400 values will be as follows:

- 1401 • For cytotoxicity testing (per ISO 10993-5):
 - 1402 - the positive control material is \geq Grade 3
 - 1403 - the negative control material is Grade 0
- 1404 • For intracutaneous reactivity irritation testing:
 - 1405 - the sodium chloride control is Grade 0
 - 1406 - the oil control is \leq Grade 2
- 1407 • For primary skin (dermal) irritation testing, the sodium chloride and oil controls is
1408 Grade 0
- 1409 • For guinea pig maximization sensitization testing (per ASTM F720):⁶⁶
 - 1410 - the sodium chloride and oil vehicle controls are primarily Grade 0 with <8%
1411 frequency Grade 1 results

⁶⁶ ASTM F720-17: *Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test*

- the positive controls are run at least biannually (for each animal source) and are at least one grade higher than concurrently run sodium chloride and oil vehicle controls in at least 81% of the animals (for strong sensitizers such as 0.1-0.5% dinitrochlorobenzene (DNCB) at induction and 0.05-0.1% DNCB at challenge)
- For closed patch sensitization testing:
 - the sodium chloride and oil vehicle controls are Grade 0.
 - the positive controls are run at least biannually (for each animal source) and are at least one Grade higher than concurrently run sodium chloride and oil vehicle controls in at least 81% of the animals (for strong sensitizers such as 0.1-0.5% DNCB at induction and 0.05-0.1% DNCB at challenge)
- For acute systemic toxicity testing, the sodium chloride and oil controls result in no adverse clinical findings, no decrease in body weight, and no deaths (per ISO 10993-11)
- For material-mediated pyrogenicity testing there are no predefined criteria
- For hemolysis testing (per ASTM F756):
 - the positive control material is $\geq 5\%$ hemolytic index
 - the negative control material is $< 2\%$ hemolytic index
- For complement activation testing using SC5b-9 (a product of the terminal pathway for complement activation),
 - the positive control meets one of the following criteria:
 - cobra venom factor positive control (if applicable) is at least 10X greater than both the negative control material and the activated normal human serum or whole blood, or
 - the positive material control (if applicable) is statistically significantly higher than both the negative control material and the activated normal human serum or whole blood,
 - any kit-specific high and low controls meets the kit specifications.

7.8 Reporting of results

- a) The applicant organization agrees that it will have procedures to record all required information in ISO/IEC 17025, as applicable, for each test conducted, including the following:
 - Test procedure(s) and test standard(s) used
 - Product or component(s) tested
 - Test equipment used for testing, measurement, or review (including the equipment's ratings and accuracies, unless otherwise readily available)
 - Date of the test(s). For example, periodic controls may have different test dates
 - Test report number, including revision number and amendment date, if applicable, and any related sub-contracted test report number(s)
 - Name of the personnel performing the test(s) and for biological studies, the signature of the study director and quality assurance unit personnel (i.e., per 21 CFR part 58, Good Laboratory Practices for Nonclinical Laboratory Studies, requirements)

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- The test conditions as specified by the test standard, if applicable, (e.g., required voltage, power, temperature, or humidity for the test)
 - Sample preparation:
 - images of device (or representative portion, if full device is not used) prior to and post sample preparation
 - sample cutting, if applicable
 - Extraction conditions, if applicable:
 - extraction vehicle, time, temperature, and test article/vehicle ratio
 - storage time and temperature prior to use
 - images of vehicle post-extraction (color, cloudiness, presence of particulates)
 - Sample manipulation:
 - filtration, centrifugation, dilution, pH adjustment, osmolality adjustment or other deviations from the sampling procedures
 - Any deviations from the laboratory's ASCA accepted procedures as well as any amendments to the test report
 - Test results to include:
 - opinions and interpretations included in a test report
 - all of the applicable data required by the laboratory's procedures; and
 - a statement that testing was conducted according to 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations⁶⁷

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- b) The applicant organization agrees that testing conducted by subcontractors will also comply with the above test report specifications, as applicable.
 - c) The applicant organization agrees that the test report and an ASCA Summary Test Report will be submitted to the client at the end of testing activities (*Refer to Appendix E of this guidance*).

1480 7.9 Complaints

1481 There are no additional specifications than those set forth in ISO/IEC 17025.

1482 7.10 Nonconforming work

1483 There are no additional specifications than those set forth in ISO/IEC 17025.

1484 7.11 Control of data and information management

1485 There are no additional specifications than those set forth in ISO/IEC 17025.

1486 **ISO/IEC 17025 Section 8 (“Management system requirements”)**

1487 8.1 Options

1488 There are no additional specifications than those set forth in ISO/IEC 17025.

⁶⁷ As discussed at the public workshop titled “[Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards](#),” biocompatibility testing conducted under the ASCA Pilot will be conducted in accordance with 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations.

Appendix B: ASCA Program Specifications for Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment

The following ASCA program specifications provide expectations for the accreditation of testing laboratories for basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory equipment under the ASCA Pilot. The test methods included in the ASCA Pilot for Basic Safety and Essential Performance of medical devices and laboratory equipment are (*refer to section VII.B of this guidance*) :

- ANSI/AAMI ES60601-1: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (along with the FDA-recognized collateral and particular standards in the 60601/80601 family)⁶⁸
- IEC 61010-1: *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements* (along with the FDA-recognized particular standards in the 61010 family)⁶⁸

The program specifications in this Appendix are specific to the ASCA Pilot and are *in addition* to those for voluntary conformity found in ISO/IEC 17025. A testing laboratory, to participate, is expected to meet all elements of ISO/IEC 17025 as well as the ASCA program specifications identified in this Appendix to assess basic safety and essential performance below. For readability and ease of reference, the numbering and nomenclature (including the term “requirements”) below correspond to the numbering and nomenclature of clauses/subclauses in ISO/IEC 17025. Note that the expectations below were developed with input from stakeholders at the public workshop titled “Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards.”⁶⁹ (*Refer to Section V.C. of this guidance*).

The standards included in the ASCA Pilot for Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment (*Refer to Section VII.B. of this guidance*) include more detailed information regarding test reporting (e.g., IEC test report forms (TRFs)) in comparison to the standards included in the ASCA Pilot for Biological Evaluation of Medical Devices (*Refer to Section VII.A. of this guidance*). The specificity in the existing standards is reflected in the length and detail of the corresponding ASCA program specifications.

ISO/IEC 17025 Section 4 “General requirements”

4.1 Impartiality

⁶⁸ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶⁹ ASCA Public Workshop website: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-accreditation-scheme-conformity-assessment-asca-medical-devices-fda-recognized>

1524 If any services, such as consulting, design, or research, are offered by the applicant organization,
1525 it will have a policy and procedure for maintaining impartiality through separation of those
1526 services from its testing activities.

1527 4.2 Confidentiality

1528 There are no additional specifications above those set forth in ISO/IEC 17025.

1529 **ISO/IEC 17025 Section 5 “Structural requirements”**

1530 There are no additional specifications above those set forth in ISO/IEC 17025.

1531 **ISO/IEC 17025 Section 6 “Resource requirements”**

1532 6.1 General

1533 There are no additional specifications above those set forth in ISO/IEC 17025.

1534 6.2 Personnel

1535 a) The applicant organization agrees to maintain technical personnel who are qualified and
1536 competent to:

- 1537 • Establish and carry out the appropriate test methods required for the standard.
- 1538 • Understand and apply the specifications and underlying rationale (including concepts
1539 of basic safety and essential performance).
- 1540 • Understand other normative references in the relevant standards forming part of the
1541 requested scope of accreditation.
- 1542 • Assure the suitability of means used to confirm the basic safety and essential
1543 performance of the medical device under test.

1544 b) The applicant organization agrees to:

- 1545 • maintain a written program for the initial and ongoing training of technical personnel,
1546 including procedures for applying new/updated test methods and performing required
1547 tests.
- 1548 • provide ongoing training of technical personnel at defined intervals, or when test
1549 standards or methods are updated or developed, as well as when responsibilities have
1550 changed.
- 1551 • conduct training through appropriate training mechanisms, such as on-the-job training
1552 or formal classroom training.
- 1553 • maintain written records of training for technical personnel.

1554 c) The job descriptions agree to define and document the responsibilities and required
1555 competencies of managerial, technical, and key support personnel involved in requested
1556 scope of accreditation.

1557 6.3 Facilities and environmental conditions

1558 There are no additional specifications to those set forth in ISO/IEC 17025.

1559 6.4 Equipment

- 1560 a) The applicant organization agrees to ensure that all equipment used for testing and
1561 evaluating devices is available and in proper working order for requested scope of
1562 accreditation.
- 1563 b) The applicant organization agrees to ensure that its procedures specify the steps for
1564 establishing calibration intervals for each type or item of equipment, and specify criteria,
1565 steps, and approvals for extending the calibration interval of an instrument.
- 1566 c) The applicant organization agrees to ensure that its procedures address adding, deleting,
1567 modifying, or maintaining information in equipment records in an accurate and timely
1568 manner, and specify the personnel responsible for these tasks.
- 1569 d) The applicant organization agrees to have procedures to examine the effects of defective
1570 or out-of-tolerance equipment on calibrations and tests. The applicant organization
1571 further agrees that procedures will identify the personnel responsible for such
1572 examinations, specify their responsibilities, and provide the steps for the examination,
1573 including:
- 1574 • determining whether the effects are unacceptable (including the accept/reject criteria)
 - 1575 • identifying the devices affected
 - 1576 • analyzing the particular tests impacted for these devices; and determining whether
1577 retesting is required
 - 1578 • Preparing a report of the examination
 - 1579 • Notifying customers when retesting is required; and
 - 1580 • Specifying the steps to follow to perform the retesting

1581 6.5 Metrological traceability

1582 There are no additional specifications to those set forth in ISO/IEC 17025.

1583 6.6 Externally provided products and services

1584 There are no additional specifications to those set forth in ISO/IEC 17025.

1585 **ISO/IEC 17025 Section 7 “Process requirements”**

1586 7.1 Review of requests, tenders and contracts

1587 There are no additional specifications to those set forth in ISO/IEC 17025.

1588 7.2 Selection, verification and validation of methods

- 1589 a) The applicant organization agrees that its management system will include procedures
1590 governing the development, maintenance, and use of test procedures (including
1591 associated records in paper or electronic format such as test data forms and checklists).
1592 The applicant organization further agrees that these management system procedures will
1593 include steps for:
- 1594 • ensuring that test procedures are documented and reviewed prior to use;
 - 1595 • identifying the personnel responsible for developing, reviewing, and maintaining test
1596 procedures;

- 1597 • ensuring that new and revised test procedures are reviewed by personnel who are
1598 competent and trained in the applicable standard(s); and
1599 • specifying the criteria for review.
- 1600 b) The applicant organization agrees that test procedures will include or specify, as
1601 appropriate, the:
- 1602 • unique identification, including title, document number, revision, and effective date;
 - 1603 • specific test equipment to use along with their required ratings;
 - 1604 • warnings/caution statements to alert the operators of potential hazards;
 - 1605 • normal and any unusual ambient conditions (including tolerances) for tests;
 - 1606 • test data to be obtained and recorded;
 - 1607 • objective acceptance criteria for results including the essential performance required
1608 to be maintained;
 - 1609 • testing techniques required to ensure consistent results;
 - 1610 • instructions on equipment operation and on handling and preparation of test samples
1611 (including instructions on multiple sample marking, if applicable); and
 - 1612 • the methods to be used to assess or monitor the performance of the test sample.
- 1613 c) The applicant organization agrees to ensure that relevant contextual information from the
1614 intended use of the device and manufacturers essential performance specifications,
1615 including any metrological stability, are reflected in each test procedure.
- 1616 d) The applicant organization agrees to ensure that each test procedure adequately addresses
1617 all the applicable specifications of the standard for the equipment under test.
- 1618 e) The applicant organization agrees to give preference to using test methods in the
1619 requested scope of accreditation. Alternative test methods may be used with justification,
1620 where appropriate.
- 1621 f) The application agrees to ensure that deviations from the test methods specified in
1622 standards in the ASCA Pilot are justified and documented accordingly.
- 1623 7.3 Sampling
1624 There are no additional specifications to those set forth in ISO/IEC 17025.
- 1625 7.4 Handling of test or calibration items
1626 There are no additional specifications to those set forth in ISO/IEC 17025.
- 1627 7.5 Technical records
1628 There are no additional specifications to those set forth in ISO/IEC 17025.
- 1629 7.6 Evaluation of measurement uncertainty
1630 There are no additional specifications to those set forth in ISO/IEC 17025.
- 1631 7.7 Ensuring the validity of results
1632 There are no additional specifications to those set forth in ISO/IEC 17025.

1633 7.8 Reporting of results

- 1634 a) The applicant organization agrees to have procedures to record and report all required
1635 information in ISO/IEC 17025 for each test conducted, including the following:
- 1636 • A statement of the extent to which the articles that were tested complied or did not
1637 comply with the specifications of each clause that were part of the standard tested;
 - 1638 • A detailed description of the medical device tested including accessories, options,
1639 software versions, and configurations tested;
 - 1640 • A test plan including reference to the manufacturer's stated intended use and essential
1641 performance claims monitored during testing as well as reporting of the operational
1642 state(s) of the equipment during each test;
 - 1643 • The date and location of the test(s) undertaken;
 - 1644 • The test report's unique identifier;
 - 1645 • The signatures and printed names of the personnel performing/witnessing the test(s);
 - 1646 • the test conditions, e.g., supply voltage, ambient temperature or humidity, when
1647 relevant to the test;
 - 1648 • all of the applicable data required for equipment under test according to the standard;
 - 1649 • a statement of the estimated uncertainty of measurement, when it is relevant to the
1650 validity or application of the test results, when a customer's instructions so requires or
1651 when the uncertainty affects compliance to a specification limit and
 - 1652 • a statement that test report meets ASCA program specifications.
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- 1654 b) The applicant organization agrees not to report test results in a "simplified way" as
1655 mentioned in Clause 7.8.1.3. Instead, the applicant agrees to report to the customer all
1656 information listed in Clauses 7.8.2 through 7.8.7 to the extent applicable. (Clause 7.8.4 is
1657 for calibration certificates and is not applicable when testing to the requirements of IEC
1658 60601.)
- 1659
- 1660 c) The applicant organization agrees to convey in writing to the customer all opinions and
1661 interpretations, including significant concerns about basic safety and essential
1662 performance such as:
- 1663 • Anomalous test results noted during any part of the testing that were not resolved to
1664 the testing laboratory's satisfaction.
 - 1665 • Concerns regarding any other aspect of conformity to the standard.

1666 7.9 Complaints

1667 There are no additional specifications to those set forth in ISO/IEC 17025.

1668 7.10 Nonconforming work

1669 There are no additional specifications to those set forth in ISO/IEC 17025.

1670 7.11 Control of data and information management

1671 There are no additional specifications to those set forth in ISO/IEC 17025.

1672 **ISO/IEC 17025 Section 8 "Management system requirements"**

1673 8.1 Options

1674 There are no additional specifications than those set forth in ISO/IEC 17025.

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Appendix C: Accreditation Body Application for ASCA Pilot Participation

A complete application from an accreditation body seeking to participate in the ASCA Pilot should include the following components:

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of Recognition

Indication of the requested scope of recognition from the list of selected standards and/or test methods in the ASCA Pilot (more than one standard and test method may be identified).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Pilot.

- Proof of signatory status as International Laboratory Accreditation Cooperation (ILAC) MRA whose scope includes ISO/IEC 17025.
- Confirmation that accreditation body is based in the United States.
- A current list and description of any conformity assessment services offered for which the scope includes any of the standards and/or test methods in the ASCA Pilot.
- A detailed description of the process to accredit testing laboratory applicants to ISO/IEC 17025 and ASCA program specifications; includes awareness, training, and accreditation activities.
- A detailed description of the approach to assess procedures and corrective actions as related to the most recent inspection findings noted by FDA Bioresearch Monitoring Program per 21 CFR Part 58 – Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies for testing laboratory applicants with biological evaluation of medical device standards in their scope of recognition.⁷⁰

⁷⁰ As discussed at the public workshop titled “[Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards](#),” biocompatibility testing conducted under the ASCA Pilot will be conducted in accordance with 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations.

- A detailed description of the accreditation body's approach used to determine technical competency of testing laboratories consistent with ASCA program specifications. This includes a detailed description of the qualifications for technical assessors for the requested scope of recognition. A description could include resumes, CVs, summary of experience, relevant technical training, etc., from personnel already identified.
- A detailed description of the policy and processes concerning corrective actions and the approach for responding to, investigating, and resolving complaints against testing laboratories.

D. Signed Agreement

Confirmation that the accreditation body has read, understood, and agrees to adhere to all of the following for its ASCA Pilot-related activities:

- Maintain scope of signatory status to International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) that includes ISO/IEC 17025.
- Verify conformance with ISO/IEC 17025 and ASCA program specifications when accrediting testing laboratories for the ASCA Pilot.
- Provide all ASCA Pilot accreditation documentation to FDA upon request.
- Allow FDA to participate as an observer during the accreditation body's ILAC MRA peer evaluation(s).
- Allow FDA to participate as an observer during the accreditation body's assessment of a testing laboratory.
- Commit that all relevant FDA training will be completed by appropriate individuals prior to providing any accreditation to testing laboratories under the ASCA Pilot.
- Establish and maintain appropriate communication with FDA. An accreditation body should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
 - Notification to FDA within 5 calendar days via email of any changes that may impact the accreditation body's participation (e.g., change to scope of signatory status to ILAC MRA).
 - Notification to FDA within 5 calendar days via email of any changes that may impact the participation of any of the testing laboratories that the accreditation body has accredited.
 - Attendance at regularly scheduled teleconferences with FDA as requested.
 - Provision of status updates annually or upon request to FDA including the following information regarding the accreditation body's ASCA Pilot activities:
 - Complaint handling;
 - Total number and list of testing laboratories the accreditation body has accredited including dates of accreditation;
 - Number and nature of non-conformities the accreditation body has observed during accreditation or auditing of testing laboratories;

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- Number of suspensions issued by the accreditation body for testing laboratories; and
 - Results of the accreditation body’s internal and management reviews.
 - Establish and maintain policies and procedures that incorporate feedback from FDA.
 - Acknowledge that FDA maintains complete discretion regarding recognizing an accreditation body’s participation in the ASCA Pilot. FDA may withdraw recognition at any time.
 - Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.

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Appendix D: Testing Laboratory Application for ASCA Pilot Participation

A complete application from a testing laboratory seeking to participate in the ASCA Pilot should include the following components. If a testing laboratory application will be for multiple testing sites, documentation should be clear with respect to the site to which it applies.

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of Recognition

Indication of the requested scope of recognition from the list of selected standards and/or test methods in the ASCA Pilot (more than one standard and test method may be chosen).

C. Information in Support of Competence

- Information demonstrating ability to participate in the ASCA Pilot.
- Proof of testing laboratory accreditation that shows:
 - The accreditation is from an accreditation body participating in the ASCA Pilot.
 - The scope of recognition for the accreditation body includes the scope for which they accredited the testing laboratory.
 - The scope of accreditation provided by the accreditation body to the testing laboratory matches the testing laboratory's requested scope of recognition.
- A copy of the Index of SOPs and any relevant ASCA test-related documents (e.g., SOPs, work instructions, master protocols, test-specific protocols, data collection worksheets, training information) applicable to any biological evaluation of medical device standards and/or test methods if included in the requested scope of recognition.

D. Signed Agreement

Confirmation that the testing laboratory has read, understood, and agrees to adhere to all of the following for its ASCA Pilot-related activities:

- Conduct testing in accordance with ISO/IEC 17025 and ASCA program specifications.

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- Abide by the ASCA program specifications to achieve and maintain status as an ASCA-accredited testing laboratory.
 - Allow FDA to conduct audits upon request; audits may include observations of testing activities and documentation review.
 - Establish and maintain appropriate communication with FDA. A testing laboratory should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
 - Notification to FDA within 5 calendar days via email of any changes that may impact the testing laboratory's participation.
 - Attendance at regularly scheduled teleconferences with FDA as requested.
 - Provision of annual reports of complaint handling to FDA.
 - Commit that all relevant FDA training will be completed by appropriate individuals prior to conducting testing under the ASCA Pilot.
 - Ensure that proprietary information is protected per client agreements.
 - Acknowledge that FDA maintains complete discretion regarding recognizing a testing laboratory's participation and *ASCA Accreditation* in the ASCA Pilot. FDA may withdraw recognition or *ASCA Accreditation* at any time.
 - Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.

Appendix E: ASCA Summary Test Report Examples- Biological Evaluation of Medical Devices

Note: This example is intended to illustrate the supplemental documentation that should accompany the Declaration of Conformity per FDA's guidance titled "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)."

Example 1: Biocompatibility Test: Irritation – Intracutaneous Reactivity (ISO 10993-10)

Part 1: Test Lab – Summary Test Report

ASCA Test Article Prep SOP#: [ASCATAPrep(date/version)]

- ☐ Test Article was prepared per the above protocol (no deviations/amendments); or
☐ Test was prepared per the above protocol, with the following deviations/amendments (e.g., filtering, extract manipulation, pH adjustment):

Description⁷¹

Extraction Solvent:

- ☐ 0.9% Sodium Chloride (SC)
☐ Cotton Seed Oil (CSO)/Sesame Oil (SO)
☐ Other:⁷¹ [DESCRIBE]

Extraction Ratio:

- ☐ 6cm²/ml (<0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:⁷¹ [DESCRIBE]

Extraction Conditions:

- ☐ 37°C, 72 h
☐ 50°C, 72 h
☐ 72°C, 24 h
☐ 121°C, 1 h
☐ Other:⁷¹ [DESCRIBE]

- ☐ The test article extract DID NOT change color, appear turbid or have particles.
☐ There were changes in color, turbidity or particles in the test extract or swelling/degradation of the test article.⁷¹

⁷¹ Include the complete test report with ASCA Summary Test Report Summary during the pilot (depending on the information provided, FDA may or may not need to review the complete test report). Test Lab/Manufacturer may also need to provide a rationale to support a decision on a premarket submission.

1842 **ASCA Test Method SOP #:** [ASCAIntracut(date/version)]
 1843 ☐ Test was conducted per the above protocol (no deviations/amendments) and 21 CFR 58; or
 1844 ☐ Test was conducted per the above protocol and 21 CFR 58, with the following
 1845 deviations/amendments:

*Description*⁷²

1846 **Results:**⁷³

	Test Article	24 hr Results	48 hr Results	72 hr Results	Conclusions
Animal 1	SC Test	ER [^] : 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
	SC Control	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
Animal 2	SC Test	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
	SC Control	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
Animal 3	SC Test	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
	SC Control	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	ER: 0/0/0/0/0 ED: 0/0/0/0/0	Performed as expected
Animal 1	SO Test	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/0/1/1/1 ED: 0/0/0/0/0	ER: 1/0/1/1/1 ED: 0/0/0/0/0	Performed as expected
	SO Control	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/0/0/1 ED: 0/0/0/0/0	Performed as expected
Animal 2	SO Test	ER: 1/1/1/1/1 ED: 0/0/1/0/0	ER: 1/1/1/1/0 ED: 0/0/1/0/0	ER: 1/1/1/1/0 ED: 0/0/0/0/0	Performed as expected
	SO Control	ER: 1/1/1/1/0 ED: 0/0/1/0/0	ER: 1/1/1/0/1 ED: 0/0/0/0/0	ER: 1/1/0/0/0 ED: 0/0/0/0/0	Performed as expected
Animal 3	SO Test	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/1/1/1 ED: 0/0/0/0/0	Performed as expected
	SO Control	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/1/1/1 ED: 0/0/0/0/0	ER: 1/1/1/1/1 ED: 0/0/0/0/0	Performed as expected

[INSERT ROWS FOR ANY ADDITIONAL REPEAT TEST DATA]

⁷² Include the complete test report with ASCA Summary Test Report Summary during the pilot (depending on the information provided, FDA may or may not need to review the complete test report). Test Lab/Manufacturer may also need to provide a rationale to support a decision on a premarket submission.

⁷³ Include the complete test report with ASCA Summary Test Report during the pilot, if the overall score differences between the test and control are greater than one (i.e., per ISO 10993-10:2010, Clause 6.4.7), or if there were non-zero results for the sodium chloride control, or results greater than 2 for the oil control at any timepoint.

1848 ^ER = erythema grade; ED = edema grade

Extract	Overall Test Group Mean	Overall Control Group Mean	Overall Mean Difference (Test – Control)	Conclusion
SC	0.0	0.0	0.0	Non-Irritant
SO	1.0	0.9	0.1	Non-Irritant

- 1849 ☐ There were no adverse clinical findings or animal deaths; or
1850 ☐ The following adverse clinical findings or animal deaths occurred:

*Description*⁷⁴

1851 I confirm that:

- 1852 ☐ The above summary information includes all original and any retest data; and
1853 ☐ I have checked that there are no differences between the complete test report and this
1854 summary test report.

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1858 Name: [TYPED NAME POSITION] Date

1860 ***Part 2: Medical Device Manufacturer– Summary Test Report***

1861 I confirm that:

- 1862 ☐ I have checked that there are no differences between the complete test report and this
1863 summary test report;
1864 ☐ My device does not include: absorbable and in situ polymerizing devices, liquid devices,
1865 hydrogel devices, and devices containing nanomaterials; and
1866 ☐ Information on how the test article compares with the device provided in this FDA
1867 submission (including selection of “representative” devices/portions) can be found at the
1868 following location:⁷⁵ [INSERT SUBMISSION#/SUPPLEMENT#, page#]

1869 Name: [TYPED NAME, POSITION] Date

1870

⁷⁴ Include the complete test report with ASCA Summary Test Report Summary during the pilot (depending on the information provided, FDA may or may not need to review the complete test report). Test Lab/Manufacturer may also need to provide a rationale to support a decision on a premarket submission.

⁷⁵ Please see FDA’s guidance titled “[Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"](#)” for considerations regarding the use of medical devices in their final finished form or a representative test article for biocompatibility testing.

1871 **Example 2: Biocompatibility Test:** Cytotoxicity – MEM Elution (ISO 10993-5)

1872 **Part 1: Test Lab – Summary Test Report**

1873 **ASCA Test Article Prep SOP#:** [ASCATAPrep(date/version)]

1874 ☐ Test Article was prepared per the above protocol (no deviations/amendments); or

1875 ☐ Test was prepared per the above protocol, with the following deviations/amendments (e.g.,
1876 filtering, extract manipulation, pH adjustment):

*Description*⁷⁶

1877 **Extraction Solvent:**

1878 ☐ MEM with 5-10% animal serum

1879 ☐ Other:⁷⁶ [DESCRIBE]

1880 **Extraction Ratio:**

1881 ☐ 6cm²/ml (<0.5mm thick)

1882 ☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)

1883 ☐ 1.25cm²/ml (elastomers > 1.0mm thick)

1884 ☐ Other:⁷⁶ [DESCRIBE]

1885 **Extraction Conditions:**

1886 ☐ 37°C, 72 h ☐ 50°C, 72 h ☐ 72°C, 24 h ☐ 121°C, 1 h

1887 ☐ Other:⁷⁸ [DESCRIBE]

1888 ☐ The test article extract DID NOT change color, appear turbid or have particles.

1889 ☐ There were changes in color, turbidity or particles in the test extract or swelling/degradation
1890 of the test article.⁷⁶

1891 **ASCA Test Method SOP #:** [#####-ASCACytotox(date/version)]

1892 ☐ Test was conducted per the above protocol (no deviations/amendments) and 21 CFR 58; or

1893 ☐ Test was conducted per the above protocol and 21 CFR 58, with the following
1894 deviations/amendments:

*Description*⁷⁶

1895

1896

⁷⁶ Include the complete test report with ASCA Summary Test Report Summary during the pilot (depending on the information provided, FDA may or may not need to review the complete test report). Test Lab/Manufacturer may also need to provide a rationale to support a regulatory decision.

1897 **Results:**⁷⁷

	24 hr Results (optional)	48 hr Results	72 hr Results (implants)	Conclusion
Vehicle Control	Grade 0/0/0	Grade 0/0/0	Grade 0/0/0	Performed as expected
Negative Control HDPE	Grade 0/0/0	Grade 0/0/0	Grade 0/0/0	Performed as expected
Positive Control Latex	Grade 4/4/4	Grade 4/4/4	Grade 4/4/4	Performed as expected
Test Article Extract (100% neat)	Grade 0/0/0	Grade 0/0/0	Grade 0/0/0	Non-cytotoxic
<i>[INSERT ROWS FOR ANY ADDITIONAL TEST ARTICLE DILUTION/RETEST DATA]</i>				

1898 I confirm that:

- 1899 ☐ The above summary information includes all original and any retest data; and
1900 ☐ I have checked that there are no differences between the complete test report and this
1901 summary test report.

1902 Name: [TYPED NAME POSITION]

Date

1903 ***Part 2: Medical Device Manufacturer***

1904 I confirm that:

- 1905 ☐ I have checked that there are no differences between the complete test report and this
1906 summary test report;
1907 ☐ My device does not include: absorbable and in situ polymerizing devices, liquid devices,
1908 hydrogel devices, and devices containing nanomaterials; and
1909 ☐ Information on how the test article compares with the device provided in this FDA
1910 submission (including selection of “representative” devices/portions) can be found at the
1911 following location:⁷⁸ [INSERT SUBMISSION#/SUPPLEMENT#, page#]

⁷⁷ Include the complete test report with ASCA Summary Test Report during the pilot, if there were non-zero results for the test article, vehicle control or negative control, or if there were results less than 3 for the positive control at any timepoint.

⁷⁸ Please see FDA’s guidance titled “[Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"](#)” for considerations regarding the use of medical devices in their final finished form or a representative test article for biocompatibility testing.

1912 Name: [TYPED NAME, POSITION]

Date

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Appendix F: ASCA Summary Test Report Examples - Basic Safety and Essential Performance

Note: This example is intended to illustrate the supplemental documentation that should accompany the Declaration of Conformity per FDA's guidance titled "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)."

Medical Device Manufacturer– Summary Test Report Device Essential Performance Characteristics

Description of the device essential performance characteristics supplied by the device manufacturer to the testing laboratory and which were included in the testing.

Evaluation of the Results of Conformity Assessment

- ☐ The articles that were tested are identical in all material respects to the subject device
- ☐ The test results demonstrate that the device is in conformity with the standard⁷⁹

1. Clauses Tested

- ☐ All clauses were deemed applicable and tested. No clauses had failing test results.
- ☐ The following clauses were deemed not applicable, not tested, or failed in the test results; rationale for each is provided below.

Rationale for any clause identified as not applicable, not tested, or had failing test results.

2. Anomalous Results

- ☐ Anomalous results were NOT identified by the testing laboratory as a concern
- ☐ Anomalous results were identified by the testing laboratory as a concern; resolution of results described below.

Description of resolution of anomalous test results.

3. Concerns Communicated by Testing Laboratory

- ☐ Concerns of basic safety and essential performance were NOT communicated by the testing laboratory.
- ☐ Concerns of basic safety and essential performance were communicated by the testing laboratory; resolution described below.

⁷⁹ See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.(3)(f) of FDA's guidance titled "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device](#)."

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Description of resolution of concerns identified by testing laboratory regarding any other aspects of basic safety and essential performance.

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